Factors influencing the perception of side effect risk information

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Collaborators

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(thanks to Peter Knapp for some of the content on the slides)
After taking your tablets

As with all medicines, **there may be some possible side effects** while you are taking Tenormin. Occasionally, **a few people** may suffer from the following.

Cold hands and feet, tiredness, slow heartbeat, headaches, a dry mouth, nausea, diarrhoea, disturbed sleep, thinning of the hair, mood changes, confusion, psychoses or hallucinations, bruising more easily or purplish marks on the skin, tingling hands, dry eyes, vision disturbances, skin rashes, dizziness (particularly when you stand up), impotence, or, very rarely, jaundice (yellowing of the skin or the whites of your eyes). **Some people** may also suffer from numbness and spasm in the fingers (Raynaud’s phenomenon) and heart block (which can cause dizziness or fainting).

If you suffer from any of the following conditions, they may get worse when you start to take Tenormin.

- Psoriasis.
- Breathlessness or swollen ankles, if you have heart failure.
- Asthma or breathing problems.
- Poor circulation.

Do not be alarmed by this list of possible side effects. You may not have any of them.

If you think your tablets are causing any other problems, tell your doctor or pharmacist.
Which parts of the leaflet do people read?

- Side effects: 96%
- How and when to take it: 91%
- What is your medicine for?: 85%
- Things to do before you take: 66%
- What is in your medicine?: 53%

MORI Survey for Medicines Partnership, 2003, 2004
Ask about Medicines Week
<table>
<thead>
<tr>
<th>EU</th>
<th>People</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very common</td>
<td>&gt; 10%</td>
</tr>
<tr>
<td>Common</td>
<td>1 - 10%</td>
</tr>
<tr>
<td>Uncommon</td>
<td>0.1 - 1%</td>
</tr>
<tr>
<td>Rare</td>
<td>0.01 - 0.1%</td>
</tr>
<tr>
<td>Very rare</td>
<td>&lt; 0.01%</td>
</tr>
</tbody>
</table>

What about online Information?

Using a pop-up on a medicine page of Cancerhelp.org.uk (now ‘About Cancer’ pages)

- 8 on-line studies since 2004
- Tested alternative formats for presenting side effect risk on perceptions of risk
- Controlled design with random allocation
- *Taxol, Ibuprofen, Tamoxifen*
- Approximately 15 participants per month
- Participants more likely to have a personal interest
## Characteristics of the combined samples

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td>568 Female; 21 Male; 2 missing</td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td>Mean 46.5 (SD 10.8). Range 15-66</td>
</tr>
<tr>
<td><strong>Location</strong></td>
<td>428 UK; 93 USA; 70 Other</td>
</tr>
<tr>
<td><strong>English as first language</strong></td>
<td>573 Yes; 17 No; 1 Missing</td>
</tr>
<tr>
<td><strong>Reason for visiting the webpage</strong></td>
<td>230 (38.9%) Currently taking Tamoxifen</td>
</tr>
<tr>
<td></td>
<td>50 (8.5%) Have cancer but not taking Tamoxifen</td>
</tr>
<tr>
<td></td>
<td>32 (5.4%) Have previously taken Tamoxifen</td>
</tr>
<tr>
<td></td>
<td>110 (18.6%) Were about to take Tamoxifen</td>
</tr>
<tr>
<td></td>
<td>97 (16.4%) Have a close relative or friend with cancer</td>
</tr>
<tr>
<td></td>
<td>31 (5.2%) Health professionals</td>
</tr>
<tr>
<td></td>
<td>41 (6.9%) None of the above, just looking</td>
</tr>
</tbody>
</table>
• Broadly, the suite of studies have tested the effect of stating the risk of side effects as verbal descriptors, percentages and frequency statements and combinations of these formats.

• Started off with the premise that ‘Natural Frequencies’ are more concrete and would probably work better

• *e.g. If 100 people took this medicine, 3 would get constipation.*
Cancer Research UK studies
Findings

• The evidence suggests that verbal descriptors ("common"/"rare") on their own produce markedly less accurate estimations of risk

• Percentages generally perform well, but some evidence that these are not so good for low risks

• More specific statements about frequency show some superiority over frequency bands ("affects more than 1 in 10 patients") but may not be so feasible

• People prefer combined statements ("affects 1 in 500 people (0.2%)") but are no more accurate in their estimation of risk
Common side effects
More than 10 in every 100 people have one or more of these.

- **Hot flushes and sweats** – around 45% of women have moderate to severe hot flushes and sweats while taking tamoxifen
- Changes to your periods – if you haven’t had your menopause your periods may become irregular. Some women find that their periods stop. They usually start again within 6 to 12 months of treatment finishing. However, for some women who are close to the time of their natural menopause they don’t start again
- **Fatigue (tiredness)** affects about 1 out of 4 women (25%)
- Discharge from the vagina, dryness and itching affect about 1 in 10 women – tell your doctor or nurse if you have any of these side effects
- Feeling light headed – do not drive or operate machinery if you have this
- Eye problems can very occasionally occur, such as eyesight changes, cataracts or changes in the back of the eye (retina) – it is important to have regular eye check ups while having tamoxifen. If you notice any changes in your eyesight tell your doctor
4. Possible side effects

Like all medicines, Pandemrix can cause side effects, although not everybody gets them.

Allergic reactions may occur following vaccination, in rare cases leading to shock. Doctors are aware of this possibility and have emergency treatment available for use in such cases.

In the clinical studies with a similar vaccine, most side effects were mild in nature and short term. The side-effects are generally similar to those related to the seasonal flu vaccine.

The frequency of possible side effects listed below is defined using the following convention:

- **Very common** (affects more than 1 user in 10)
- **Common** (affects 1 to 10 users in 100)
- **Uncommon** (affects 1 to 10 users in 1,000)
- **Rare** (affects 1 to 10 users in 10,000)
- **Very rare** (affects less than 1 user in 10,000)

These side effects usually disappear within 1-2 days without treatment. If they persist, consult your doctor.

The side effects listed below have occurred in the days or weeks after vaccination with vaccines given routinely every year to prevent flu. These side effects may occur with Pandemrix.

Some of these side effects are serious. If any of these occur, please tell your doctor or nurse immediately.

Uncommon
- Generalised skin reactions including urticaria (hives)

Rare
- Allergic reactions leading to a dangerous decrease of blood pressure, which, if untreated, may lead to shock. Doctors are aware of this possibility and have emergency treatment available for use in such cases.
  - **Fits**
  - Severe stabbing or throbbing pain along one or more nerves
  - Low blood platelet count which can result in bleeding or bruising

Very rare
- Vasculitis (inflammation of the blood vessels which can cause skin rashes, joint pain and kidney problems)
- Neurological disorders such as encephalomyelitis (inflammation of the central nervous system), neuritis (inflammation of nerves) and a type of paralysis known as a Guillain-Barre Syndrome

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

These measures will help to protect the environment.

6. Further Information

What Pandemrix contains
- Active substance: Split influenza virus, inactivated, containing antigen* equivalent to:
  - A/California/7/2009 (H1N1)-like strain
  - 3.75 micrograms** per 0.5 ml dose
  - Propagated in eggs
  - **expressed in microgram haemagglutinin

This vaccine complies with the WHO recommendation and EU decision for the pandemic.

- **Adjuvant:**
  - The vaccine contains an ‘adjuvant’ AS03 to stimulate a better response. This adjuvant contains squaleane (10.69 milligrams), DL-α-tocopherol (11.86 milligrams) and polysorbate 80 (4.86 milligrams).

- **Other ingredients:**
  - The other ingredients are: polysorbate 80, octoxynol 10, thiomersal, sodium chloride, disodium hydrogen phosphate, potassium dihydrogen phosphate, potassium chloride, magnesium chloride, water for injections

What Pandemrix looks like and contents of the pack

Suspension and emulsion for emulsion for injection

The suspension is a colourless light opalescent liquid

The emulsion is a whitish homogeneous
Combined verbal and numerical expressions increase perceived risk of medicine side-effects: a randomized controlled trial of EMA recommendations

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*Senior Lecturer, Department of Health Sciences, University of York, York, †Senior Lecturer, Institute of Psychological Sciences, University of Leeds, Leeds and ‡Head of Cancer Web Content, Cancer Research UK, London, UK
Testing EMA recommendations

- EMA requires a combination of words and frequency bands
  
  *Common: may affect up to 1 in 10 people*

- NICE suggest that verbal descriptors should not be used without numerical information

- It could be argued that these recommendations are on the basis of consensus, not evidence
Testing EMA recommendations

• Two questions:
  • Does the use of the verbal descriptor ‘frame’ patients’ understanding leading to overestimation of risk?
  • Does the use of two indicators of uncertainty lead to confusion?
    ‘may affect’ and ‘up to 1 in 10’
  • Compare with
    ‘will affect’ and ‘up to 1 in 10’
Testing EMA recommendations

• 2 x 2 factorial design
  • Numerical format vs. Combined verbal and numerical
  • ‘will affect’ vs. ‘may affect’

• Presented with information on 10 potential side effects; 2 each from the 5 EC frequency bands

• Asked to provide risk estimates for 5 of the side effects; 1 from each of the bandings
Figure 1: Scenario given to participants and an example of the 4 allocated formats

“In this imaginary situation your doctor has told you that you need to take the medicine Paclitaxel (Taxol) as part of your treatment for cancer.

Please read the information below about Paclitaxel and answer the questions that follow. You can look at the information again when answering the questions. We are interested in your first thoughts. Please don’t spend too long thinking about your answers.

Paclitaxel has some side effects which differ in terms of the chance of occurring. These include:

Very common: may affect more than 1 in 10 people
- Bruising more easily.
- Aching joints and muscles.

Common: may affect up to 1 in 10 people
- Mild skin rash.
- Severe anaemia (causing tiredness and breathlessness).

Uncommon: may affect up to 1 in 100 people
- Serious allergic reaction.
- Blood clots.

Rare: may affect up to 1 in 1,000 people
- Muscle weakness in arms, hands, legs.
- Itching.

Very rare: may affect up to 1 in 10,000 people
- Hearing or sight disturbances.
- Dizziness or fits.”

(The example above shows one of four risk expressions: the combined verbal and numerical risk expression, using the word ‘may’. Half the participants saw risk expressions that included the verbal terms and half saw numerical-only terms (eg. ‘May affect up to 1 in 10 people’). In addition half saw expressions that featured the words ‘will affect...’ and half those including the words ‘may affect.’).
Testing EMA recommendations

• 339 participants
  • Numerical + may = 91
  • Combined + may = 85
  • Numerical + will = 77
  • Combined + will = 86
Table 1: Sample characteristics (n=339)

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td>231 (76.7%) female; 70 (23.3%) male; n=38 not stated</td>
</tr>
<tr>
<td>Age</td>
<td>Mean 48.5 (SD 13.1); median 49; range 16-80. n= 33 not stated</td>
</tr>
<tr>
<td>Location</td>
<td>239 (77.3%) UK; 70 (22.7%) non-UK (29 USA; 15 Australia; 6 New Zealand; 5 India; 4 Canada; 3 Republic of Ireland; 2 Belgium; 1 participant each from Austria, Denmark, France, Italy, Malaysia, Switzerland); 30 not stated.</td>
</tr>
<tr>
<td>English as first language</td>
<td>289 (93.2%) Yes; 21 (6.8%) No; n=29 not stated</td>
</tr>
<tr>
<td>Reason for visiting the webpage</td>
<td>24 (7.7%) Currently taking Taxol</td>
</tr>
<tr>
<td></td>
<td>61 (19.7%) Have cancer but not taking Taxol</td>
</tr>
<tr>
<td></td>
<td>19 (6.1%) Have previously taken Taxol</td>
</tr>
<tr>
<td></td>
<td>12 (3.9%) About to start taking Taxol</td>
</tr>
<tr>
<td></td>
<td>82 (26.5%) Have a close relative or friend with cancer</td>
</tr>
<tr>
<td></td>
<td>50 (16.2%) Healthcare professional</td>
</tr>
<tr>
<td></td>
<td>61 (19.7%) None of the above</td>
</tr>
<tr>
<td></td>
<td>30 Not stated</td>
</tr>
<tr>
<td>Highest educational qualification</td>
<td>9 (2.9%) No formal qualification</td>
</tr>
<tr>
<td></td>
<td>19 (6.1%) GCSE / O Level / qualification typically gained at age 16</td>
</tr>
<tr>
<td></td>
<td>36 (11.6%) A Level / qualification typically gained at age 18</td>
</tr>
<tr>
<td></td>
<td>134 (43.4%) University degree</td>
</tr>
<tr>
<td></td>
<td>101 (32.7%) Professional qualification</td>
</tr>
<tr>
<td></td>
<td>10 (3.2%) Other; 30 Not stated</td>
</tr>
</tbody>
</table>
Testing EMA recommendations

• Asked to provide risk estimates for 5 of the side effects; 1 from each of the bandings and a rating of the perceived risk of experiencing ANY of the side effects

• Also completed 5 Likert scales regarding:
  • Satisfaction with the information
  • Severity of the side effects
  • Likelihood of experiencing a side effect
  • General risk to health
  • Effect on decision to continue treatment
## Results

### Numerical vs. Combined

Table 2: All participants’ responses (mean, SD), according to verbal and numerical format versus numerical alone

<table>
<thead>
<tr>
<th></th>
<th>Verbal and numerical term</th>
<th>Numerical term only</th>
<th>Relative risk estimate increase: verbal + numerical &gt; numerical only</th>
<th>ANOVA F-value (p)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Side effect risk estimates (actual %)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Personal chance of aching joints &amp; muscles (60%)</td>
<td>23.1 (25.4) 135</td>
<td>13.2 (15.7) 135</td>
<td>+ 75.0%</td>
<td>14.90 (.001)</td>
</tr>
<tr>
<td>Personal chance of severe anaemia (6%)</td>
<td>14.7 (17.0) 145</td>
<td>11.2 (10.7) 138</td>
<td>+ 31.2%</td>
<td>4.17 (.042)</td>
</tr>
<tr>
<td>Personal chance of serious allergic reaction (0.1 – 1%)</td>
<td>4.2 (9.5) 144</td>
<td>2.3 (8.3) 142</td>
<td>+ 82.6%</td>
<td>3.04 (.082)</td>
</tr>
<tr>
<td>Personal chance of itching (0.01 – 0.1%)</td>
<td>5.2 (15.4) 143</td>
<td>1.6 (8.6) 133</td>
<td>+ 225%</td>
<td>5.74 (.017)</td>
</tr>
<tr>
<td>Personal chance of dizziness or fits (&lt;.01%)</td>
<td>3.3 (11.4) 139</td>
<td>1.4 (9.6) 131</td>
<td>+ 135.7%</td>
<td>2.14 (.149)</td>
</tr>
<tr>
<td>Personal chance of having ANY side effect</td>
<td>31.1 (30.6) 137</td>
<td>18.7 (19.4) 132</td>
<td>+ 66.3%</td>
<td>15.48 (&lt;.001)</td>
</tr>
</tbody>
</table>

**Likert scale items**

<table>
<thead>
<tr>
<th></th>
<th>M (SD)</th>
<th>n</th>
<th>M (SD)</th>
<th>n</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Satisfaction with side effect information</td>
<td>4.4 (1.3) 159</td>
<td>4.3 (1.4) 155</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>How bad overall are Taxol side effects</td>
<td>3.4 (1.0) 159</td>
<td>3.4 (1.1) 156</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Likelihood of having a side effect</td>
<td>3.8 (1.4) 159</td>
<td>3.4 (1.4) 155</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>General risk to health from Taxol</td>
<td>3.2 (1.0) 158</td>
<td>3.1 (1.0) 156</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Impact of information on decision to take Taxol</td>
<td>2.7 (1.5) 158</td>
<td>2.8 (1.5) 155</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Results

• No differences between ‘may’ and ‘will’ conditions on perceptions of side effect risk

• Little difference in Likert ratings between the conditions
  • Higher perceived likelihood of experiencing side effects in the combined condition

• No evidence of interactions between the variables
## Results

‘May’ vs. ‘Will’

<table>
<thead>
<tr>
<th>Side effect risk estimates (actual %)</th>
<th>‘May affect’ risk qualifier</th>
<th>‘Will affect’ risk qualifier</th>
<th>Relative risk estimate increase: ‘may affect’ &gt; ‘will affect’</th>
<th>ANOVA F-value (p)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chance of aching joints &amp; muscles (60%)</td>
<td>18.9 (23.2) 144</td>
<td>17.2 (19.7) 126</td>
<td>+ 9.9%</td>
<td>0.44 (.51)</td>
</tr>
<tr>
<td>Chance of severe anaemia (6%)</td>
<td>13.3 (15.2) 150</td>
<td>12.6 (13.4) 133</td>
<td>+ 12.3%</td>
<td>0.17 (.68)</td>
</tr>
<tr>
<td>Chance of serious allergic reaction (0.1% – 1%)</td>
<td>3.6 (10.2) 148</td>
<td>2.8 (7.4) 136</td>
<td>+ 24.9%</td>
<td>0.52 (.47)</td>
</tr>
<tr>
<td>Chance of itching (0.01% – 0.1%)</td>
<td>3.4 (12.7) 145</td>
<td>3.5 (12.8) 131</td>
<td>- 3.7%</td>
<td>0.01 (.94)</td>
</tr>
<tr>
<td>Chance of dizziness or fits (&lt;.01%)</td>
<td>2.2 (10.5) 143</td>
<td>2.6 (10.7) 127</td>
<td>- 16.3%</td>
<td>0.10 (.75)</td>
</tr>
<tr>
<td>Chance of having ANY side effect</td>
<td>25.9 (27.4) 144</td>
<td>23.9 (25.3) 125</td>
<td>+ 8.4%</td>
<td>0.38 (.54)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Likert scale items</th>
<th>‘May affect’ risk qualifier</th>
<th>‘Will affect’ risk qualifier</th>
<th>ANOVA F-value (p)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Satisfaction with side effect information</td>
<td>4.4 (1.3) 165</td>
<td>4.3 (1.3) 149</td>
<td>0.20 (.66)</td>
</tr>
<tr>
<td>How bad overall are Taxol side effects</td>
<td>3.5 (1.1) 165</td>
<td>3.2 (1.0) 160</td>
<td>5.26 (.022)</td>
</tr>
<tr>
<td>Likelihood of having a side effect</td>
<td>3.7 (1.4) 165</td>
<td>3.6 (1.4) 149</td>
<td>0.60 (.43)</td>
</tr>
<tr>
<td>General risk to health from Taxol</td>
<td>3.2 (1.0) 164</td>
<td>3.1 (1.0) 150</td>
<td>0.26 (.61)</td>
</tr>
<tr>
<td>Impact of information on decision to take Taxol</td>
<td>2.9 (1.4) 164</td>
<td>2.7 (1.5) 149</td>
<td>1.51 (.22)</td>
</tr>
</tbody>
</table>
Conclusions

• Possible framing effect of verbal descriptors

• Variability of response suggests lack of shared understanding of risk descriptions

• Problem of overestimation still prevalent in ‘numerical only’ condition, but…
  • Low incidence rates of side effects mean that people are more likely to overestimate than underestimate
  • Heterogeneity of risk perception responses may mean it is impossible to get shared understanding
  • Precise risk information is difficult to obtain anyway
Implications

- Need for replication of findings with different medicines
- Are there other factors involved?
  - Numeracy
  - Other individual differences
  - Emotional reaction to different types of treatment
- Need to investigate the effect on actual behaviour
Numeracy was measured in four ‘Tamoxifen’ studies. Data combined (N=591) and accuracy of risk estimate for each of four side effects was correlated with numeracy score and subjective ratings of the information. 

Please answer some questions on how you think about certain kinds of numbers. Try to be as accurate as you can but don't worry if you find it hard, just give your best guess. Remember, your responses are anonymous.

1) Imagine that we flip a fair coin 1,000 times. What is your best guess about how many times the coin would come up heads?

2) In an imaginary lottery, the chance of winning a prize is 1%. If 1,000 people each buy a single ticket, how many would win a prize?

3) In an imaginary sweepstake, the chance of winning a car is 1 in 1,000. What percent of tickets in the sweepstake wins a car?

4) What does 40 percent mean?
   a) One quarter
   b) 4 out of 10
   c) every 40th person

Adapted from Lipkus, Samsa and Rimer (2001), and Gigerenzer (2002).
### Correlations between numeracy and accuracy of risk estimate (excluding participants with missing data)

<table>
<thead>
<tr>
<th></th>
<th>Whole sample (n=591)</th>
<th>Those who have cancer (n=461)</th>
<th>Those who have not had cancer (n=130)</th>
<th>Those who have taken/are taking tamoxifen (n=262)</th>
<th>Those who have not taken tamoxifen (n=329)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hot Flashes †</td>
<td>-.09</td>
<td>-.15**</td>
<td>-.08</td>
<td>-.25**</td>
<td>-.03</td>
</tr>
<tr>
<td>Cataracts</td>
<td>-.24**</td>
<td>-.27**</td>
<td>-.17</td>
<td>-.31**</td>
<td>-.20**</td>
</tr>
<tr>
<td>Deep Vein Thrombosis</td>
<td>-.41**</td>
<td>-.44**</td>
<td>-.29**</td>
<td>-.44**</td>
<td>-.39**</td>
</tr>
<tr>
<td>Pulmonary Embolism</td>
<td>-.48**</td>
<td>-.50**</td>
<td>-.38**</td>
<td>-.50**</td>
<td>-.46**</td>
</tr>
<tr>
<td>Risk of self getting any side effect</td>
<td>-.02</td>
<td>-.04</td>
<td>.002</td>
<td>-.08</td>
<td>.04</td>
</tr>
<tr>
<td>Risk of average person getting any side effect</td>
<td>.03</td>
<td>-.003</td>
<td>.03</td>
<td>-.04</td>
<td>.07</td>
</tr>
</tbody>
</table>

** Correlation is significant at the 0.01 level (2-tailed).
* Correlation is significant at the 0.05 level (2-tailed).
## Numeracy and the Cancer Research UK studies (cont.)

<table>
<thead>
<tr>
<th>Numeracy level (score on numeracy test)</th>
<th>N</th>
<th>Mean accuracy (sd)</th>
<th>% correct estimates (across all side effects)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zero</td>
<td>12</td>
<td>36.7 (22.4)</td>
<td>0</td>
</tr>
<tr>
<td>1</td>
<td>53</td>
<td>23.9 (21.3)</td>
<td>1.6</td>
</tr>
<tr>
<td>2</td>
<td>133</td>
<td>23.3 (20.8)</td>
<td>6.9</td>
</tr>
<tr>
<td>3</td>
<td>169</td>
<td>14.9 (16.1)</td>
<td>10.4</td>
</tr>
<tr>
<td>4</td>
<td>224</td>
<td>10.7 (12.6)</td>
<td>20.2</td>
</tr>
</tbody>
</table>
Thankyou!

“I didn’t experience any of the side effects listed in the enclosed literature. Should I be concerned?”
References


