1 (a) The assembly could fail if the peg fails to achieve: (i) a clearance fit through either of the two plates; (ii) an interference fit with the retaining washer; and (iii) fails to achieve the required longitudinal overlap with the retaining washer. [20%]

(b) The failure rates for all the above conditions can be calculated independently due to the random selection of the components. The failures total 10.77% of the assemblies formed. Details are given in the table below. [40%]

ORIGINAL DIMENSIONS								
	mean (mm)	min (mm)	max (mm)	range (mm)	stdev (mm)	z	f(z)	%
DIAMETER								
peg	10.00	9.90	10.10	0.20	0.03			
plate 1	10.20	10.00	10.40	0.40	0.07			
plate 2	10.20	10.00	10.40	0.40	0.07			
washer	9.80	9.70	9.90	0.20	0.03			
plate 1 - peg	0.20				0.07	2.683	0.0036	0.36%
plate 2 - peg	0.20				0.07	2.683	0.0036	0.36%
peg - washer	0.20				0.05	4.243	0.0000	0.00%
sub total								0.73%
LENGTH								
peg	21.50	21.00	22.00	1.00	0.17			
plate 1	8.00	7.75	8.25	0.50	0.08			
plate 2	8.00	7.75	8.25	0.50	0.08			
washer	5.00	4.00	6.00	2.00	0.33			
peg - ph1 - ph2	5.50				0.20			
peg' - washer	0.50				0.39	1.279	0.1004	10.04%
TOTAL								**10.77%**

(c) The failures due to the lack of longitudinal overlay of the peg and the retaining washer can be eliminated by increasing the length of the peg. Increasing the length by 1 mm is sufficient to make this change. The 0.15% target can be achieved by assigning one third of this limit to each of the remaining three failure modes. Details are given in the table below. [30%]

MODIFIED DIMENSIONS								
	mean (mm)	min (mm)	max (mm)	range (mm)	stdev (mm)	z	f(z)	%
DIAMETER								
peg	9.96	9.86	10.06	0.20	0.03			
plate 1	10.20	10.00	10.40	0.40	0.07			
plate 2	10.20	10.00	10.40	0.40	0.07			
washer	9.80	9.70	9.90	0.20	0.03			
plate 1 - peg	0.24				0.07	3.287	0.0005	0.05%
plate 2 - peg	0.24				0.07	3.287	0.0005	0.05%
peg - washer	0.15				0.05	3.288	0.0005	0.05%
sub total								0.15%
LENGTH								
peg	22.50	22.00	23.00	1.00	0.17			
plate 1	8.00	7.75	8.25	0.50	0.08			
plate 2	8.00	7.75	8.25	0.50	0.08			
washer	5.00	4.00	6.00	2.00	0.33			
peg - ph1 - ph2	6.50				0.20			
peg' - washer	1.50				0.39	3.838	0.0001	0.01%
TOTAL								**0.16%**

(d) The above calculations assume that the plates are flat and that the forces required to assemble the peg/washer joint can be directly applied to the assembly. The retaining force would also have to be compared to the expected axial forces on the peg in use, i.e. if bending moments are applied to the joint, what are the resultant forces on the joint? [10%]

2 (a) Key elements of good risk management might include:

1. careful assessment of the requirements for the new service;
2. careful planning and design of the change in service;
3. piloting of the proposed triaging arrangements to provide evidence of their effectiveness;
4. definition of service performance metrics and associated monitoring methods;
5. risk analysis of the new service and transition arrangements;
6. consideration of the effect of the new service on other (e.g. GP) services;
7. communication of changes to prospective patients, GPs and other stakeholders. [50%]

(b) Key risks might include:

(i) insufficient evidence of effectiveness of new approach;
(ii) lack of available competent staff to deliver the service;
(iii) insufficient training for staff on new service;
(iv) lack of availability of appointments for patients redirected to GPs;
(v) lack of guidance on new triaging system;
(vi) new system does not deter patients attending for GP-related issues;
(vii) new system deters patients with serious issues attending A&E;
(viii) overstaffing of the emergency unit;
(ix) other ... [20%]

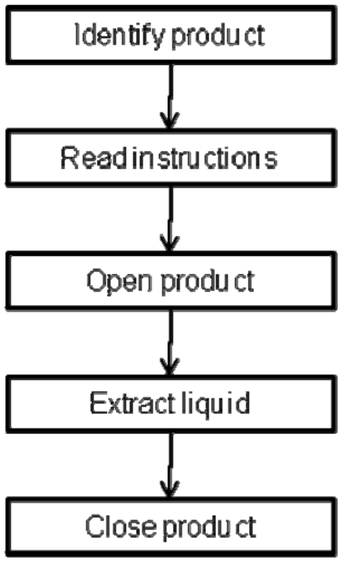
(c) A strategy that evidences the effectiveness of the new services and generates clear plans for its implementation, based on careful resource planning, staff training and education for patients, would be more likely to succeed. [30%]

3 (a) The statement could of the form: Devise a means to exclude children from opening a product containing liquid. [10%]

(b) Key requirements for the new packaging should include reference to some or all of the following:

- Container should exclude children
- Container should allow easy access to as many adults as possible
- Instructions should be clear to adults
- Warnings regarding contents should be clear
- Product should be resealable
- Evidence of tampering might be desirable [20%]

(c) A process function structure for such a product should be relatively simple, but should make reference to the use of instructions and resealing the product.

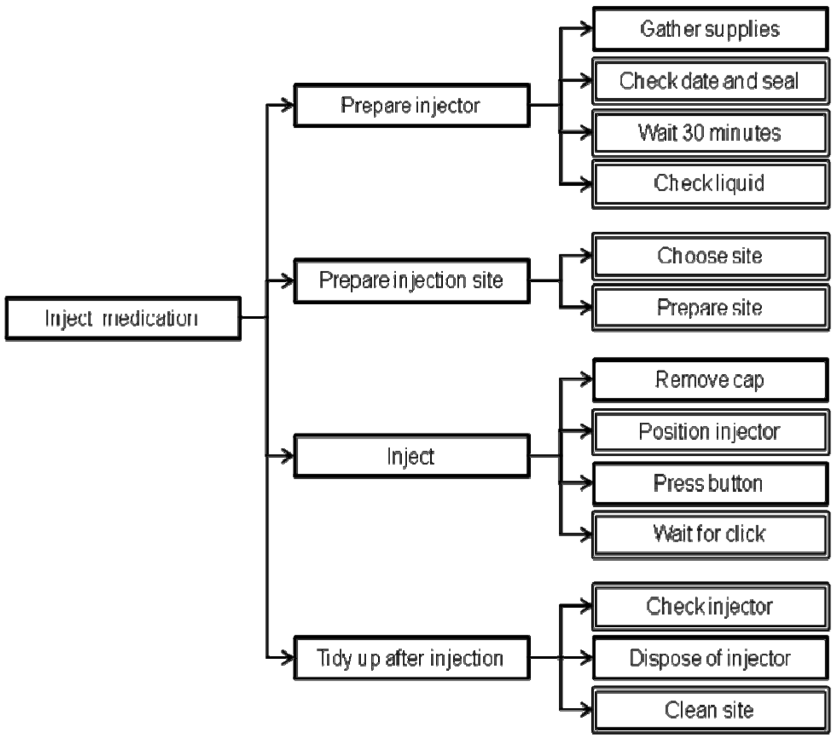


[20%]

(d) There are a number of possibilities here, accepting that this is a difficult problem to solve well. Marks given for solutions that clearly meet the requirements and are communicated well. The majority of marks are to be gained for solutions which exclude children and not adults, even in the presence of instructions. Solutions are likely to rely on the difference in hand sizes and strength between children and adults, and potentially the difference in cognitive skill, although this might also exclude some adults. There are no obvious winning solutions here and credit will be given to those who demonstrate a real understanding of the challenge in their solution. [50%]

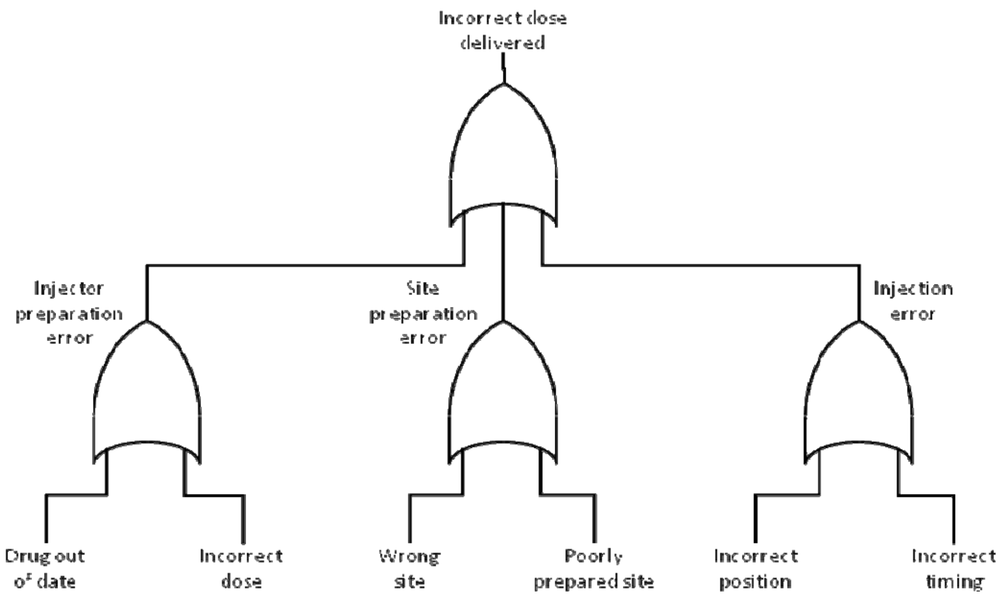
4 (a) The FAST diagram is used to describe the functional breakdown of a proposed system or product. The overall function is described as a single block on the left of the diagram. This may be decomposed, in steps to the right, to describe HOW the overall function and subsequent sub-functions may be achieved. Steps to the left then describe WHY a particular function is required. The vertical ordering of the diagram is not specified, but often describes the cycle of use or broader lifecycle of the product. [20%]

(b) A typical fast diagram will most likely follow the existing structure of draft instructions. Critical task have double line. Most tasks are critical.



[20%]

(c) A typical fault tree will broadly follow the form of the FAST diagram. All 'gates' in the tree are likely to be OR gates.



[30%]

(d) There are many possible questions, including:

1. How to check the seal?
2. How to check the liquid level? What level is appropriate?
3. What is a good injection site?
4. How to prepare the site for the injection?
5. How to identify the cap?
6. At what angle to hold the device to the skin?
7. When does the first “click” happen?
8. What is the viewing window? What to look for?
9. How to dispose of the injector?
10. What to do if something goes wrong?

Note, typical injector instructions contain all this advice and much more. [30%]