1. My comments relate primarily to the cost-benefit analysis contained within the Regulatory Impact Assessment.

2. The current supply of organs available for transplant is roughly 41 short of current levels of demand – based on numbers of patients who died while waiting for transplant. It is estimated that the new legislation would result in 15 more donors per year – an increase of 25% and an additional supply of 45 organs available for use in transplantation.

3. The cost-benefit assessment of the soft opt-out system indicated that the predicted increase in donor organs would not incur additional costs in terms of impact on critical care, surgical services including theatre time. However, hospitals are currently operating at capacity levels that allow for no additional procedures given the demands on staff time and the system in general. It is difficult to predict when the potential donors would become available with consequential problems in planning when the relevant procedures would be taking place. It is therefore possible to envisage a situation where it would not be possible to undertake the procedure and the potential donor organ might not materialise and the potential beneficiary not receive the benefits which the policy and the bill is seeking to ensure. Alternatively, the procedure will take place but at the cost of other procedures being cancelled and patients having to face the prospect of additional delays in their waits for surgery.

4. It is not clear whether the policy – if successful - will result in the need for additional staff resources or additional training requirements across Wales.

5. The situation whereby the level of supply of organs exceeds levels of demand in Wales need to be factored into the cost-benefit analysis – the system of charging other systems for transport etc. of donor organs, for example, to increase their respective levels of transplantation warrant consideration.

6. The administration costs of the soft opt-out system need to be considered relative to the current system of organ donation, while the additional costs resulting from an increased number of transplants would be managed by the Health Boards – additional pressure on already stretched resources possibly! However, it has to be recognised that there will be health benefits that emerge as a result of the policy which is the primary goal of the NHS – that is to enhance health status as opposed to ‘making money’!

7. The costs of transplantation, those that are incurred to minimise risk of rejection and ongoing treatment costs need to be compared with the costs offset as a result of the transplant e.g dialysis and on-going patient management costs. This is done in the cost-benefit analysis of the soft opt-out scheme using Department of Health data – but which seemed somewhat dated (2005/06 prices). A more recent analysis using Welsh data might be an advantage.

8. The benefits of transplants were translated into Quality Adjusted Life Years (QALYs) – which is the accepted currency for assessing health gain – although the valuation of £60,000 for each QALY gained (again based on Department of Health estimates) does seem excessive when compared with the NICE QALY threshold of £20,000 - with increased valuations for end-of-life therapies.
9. It is important to state however that the economic issues are but one feature that need to be taken into consideration in assessing this particular policy initiative – and economic appraisal cannot do justice to all of the factors that need to be included in any evaluation of this policy.

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