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Are You vMad To Go For Surgery? Risk Assessment for Transmission of vCJD via Surgical Instruments: The Contribution of System Dynamics

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Abstract

This paper describes the application of system dynamics to assess the risk of transmission of vCJD (a human form of "Mad Cow Disease") via surgical instruments. This was undertaken on behalf of the UK Department of Health and contributed to officially published reports by the UK government. System dynamics modelling helped simulate potential transmission rates and the impact of mitigation policies on the general population. A wide-ranging review group (medical and modelling experts) undertook a very detailed verification and validation exercise on models used in the study. The paper reviews the modelling process, and illustrates how system dynamics can be effectively used in conjunction with static spreadsheet models.

The Study

In February 2001, the UK Department of Health published a report on the risk assessment for transmission of vCJD via surgical instruments[1]. The published risk assessment was undertaken by the Economics and Operational Research Division (EOR4) of Department of Health reporting to the Chief Medical Officer and reviewed by the Spongiform Encephalopathy Advisory Committee (SEAC). HVR Consulting Services Ltd performed a V&V on EOR4's spreadsheet models, and provided two System Dynamics models, one of which was used in the reported study. All of the data analysis in the study was undertaken by EOR4 and other sub-contractors.

The study has been acted on by the Department of Health with the allocation of £200 million to modernise National Health Service decontamination and sterilisation facilities, and extending the employment of single-use surgical instruments for certain types of operations.

Background

Variant Creutzfeldt-Jacob Disease (vCJD) is a human form of "Mad Cow Disease". The primary source of the disease is widely accepted to have been passed to the human population

[1] Economics and Operational Research Division "Risk Assessment for Transmission of vCJD via Surgical Instruments", Department of Health, UK, Feb 2001, 81p + annexes.

through the consumption of beef containing infective material from cows suffering from Bovine Spongiform Encephalopathy (BSE).

Regardless of the source of the primary infection, the risk exists for secondary human-to-human transmission. One potential source for secondary infection is through surgical instruments during medical operations. The concern is that a patient with vCJD who is operated on may infect patents who are subsequently operated on using the same surgical instruments.

A person suffering from vCJD can have infectious material present in their bodies before the symptoms of vCJD are evident, particularly within certain organs. This material can be transferred to surgical instrument during operations. Washing of instruments does not necessarily remove all material, and autoclaving (heating) does not completely deactivate the material. Risk exists of infecting patients who are subsequently operated on using the instruments by transference of the material from the instruments to the patient.

vCJD has a long incubation period before symptoms show, so that the incidence of the disease from primary infection is difficult to determine. There are also a lot of unkowns in terms of the actual incubation period, infectivity of material passed from human to human, and the amount of deactivation of infective material through autoclaving. While the incidence from primary infection appears to be lower than initially feared, there exists a risk that the disease could become endemic in the population through secondary infection. Figures 1 and 2 show scenario runs where the disease is contained and where the disease becomes endemic. Figure 3 shows an extreme case where the disease gets out of control through secondary infection.

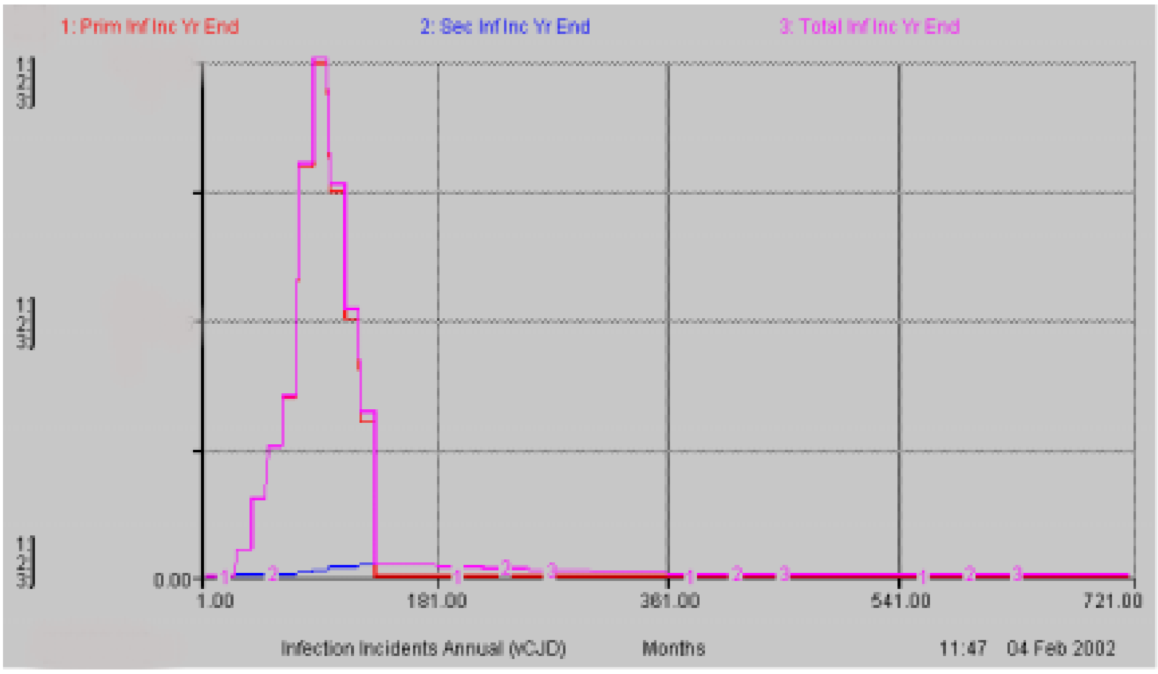

Figure 1 : Scenario where disease is contained

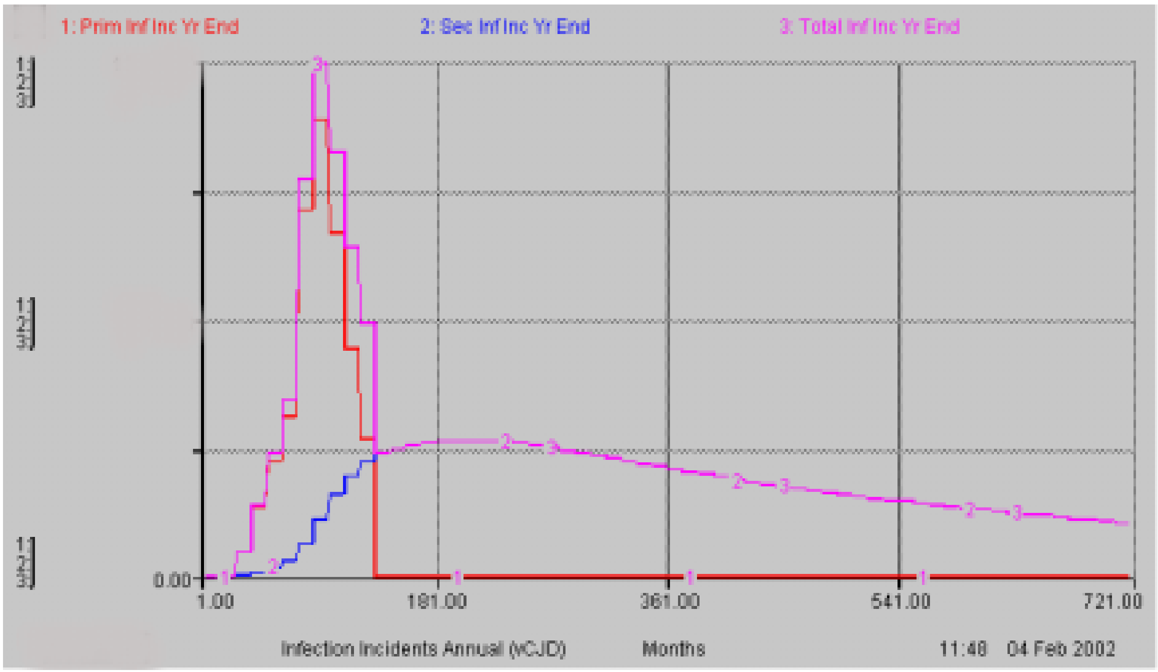

Figure 2: Scenario where disease becomes endemic

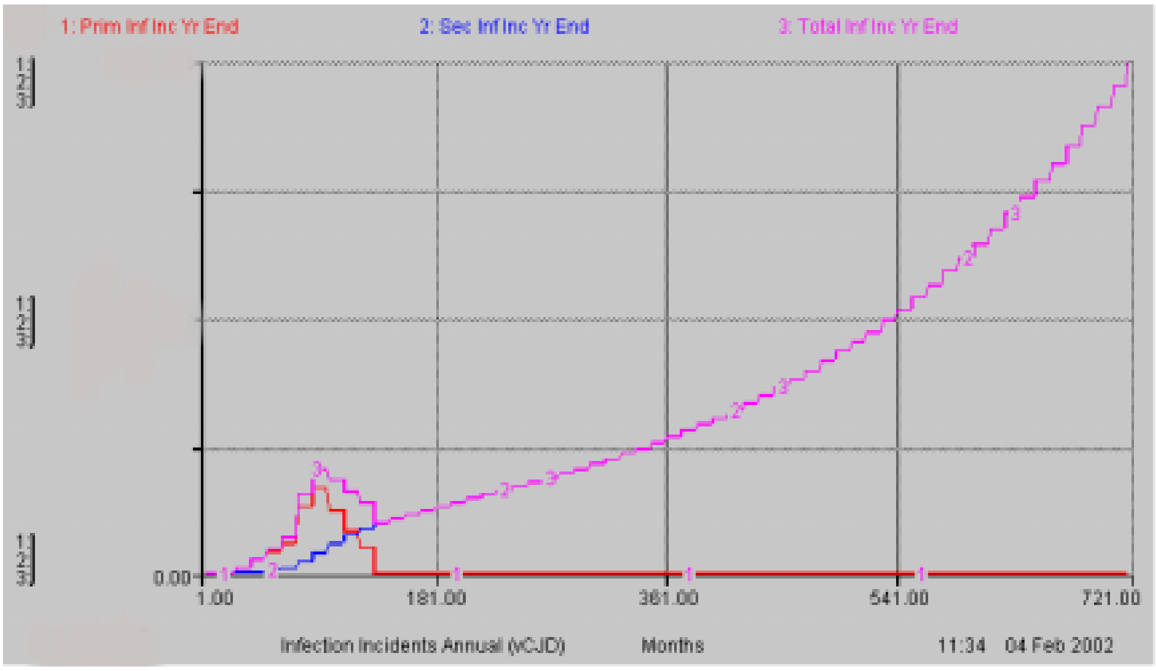

Figure 3: Extreme case – disease gets out of control

The Model Development Approach

Model development started with a static spreadsheet model developed by the Department of Health leading on to several stages of development for system dynamics models. The stages are as follows:

Stage 1 - Mathematical model developed by Department of Health to examine infections from one set of instruments used on an infected patient (spreadsheet).

Stage 2 - Snapshot model incorporates inputs on vCJD prevalence and rate of operations to determine rate of infections (spreadsheet).

Stage 3 – System dynamics model using Stage 2 calculations as a core with addition of population model to look at spread of vCJD over time (Department of Health subsequently arrayed population model by age group).

Stage 4 - Stage 2 calculations replaced by model of instrument ‘population’ for more detailed analysis (beyond scope of Feb 2001 report).

The system dynamics model developed in Stage 3 leveraged thinking that had been undertaken by the Department of Health and a spreadsheet model that had been verified and accepted by the Spongiform Encephalopathy Advisory Committee. In addition, it allowed rapid development from the static model to the dynamic model that allowed analysis of the prevalence of the disease over time, with feedback of prevalence into the risk of cross-infection. The dynamic model also allowed a number of input parameters to become time-series values indicating potential improvements in instrument handling procedures over time, and the representation of both the nature and timing of intervention policies.

Finally, the system dynamics model developed in Stage 4 was a progression of the Stage 3 model that replaced the representation of instruments (which was an implementation of the spreadsheet logic) with a flow-based, systemic representation of the instrument population. Arraying of the instrument population allows different characteristics to be specified for different types of instruments, and analysis of policies that can vary by instrument type.

Stage 3 System Dynamics Model Details

The static spreadsheet model contains a number of characteristics regarding aspects such as infectivity of material, mass of material adhering to instruments, cleaning effectiveness, etc. These were all maintained in the system dynamics model with some becoming tim- series, and a number of additional parameters were added regarding the population and disease incubation. Figure 4 summarises the parameters included in different parts of the model.

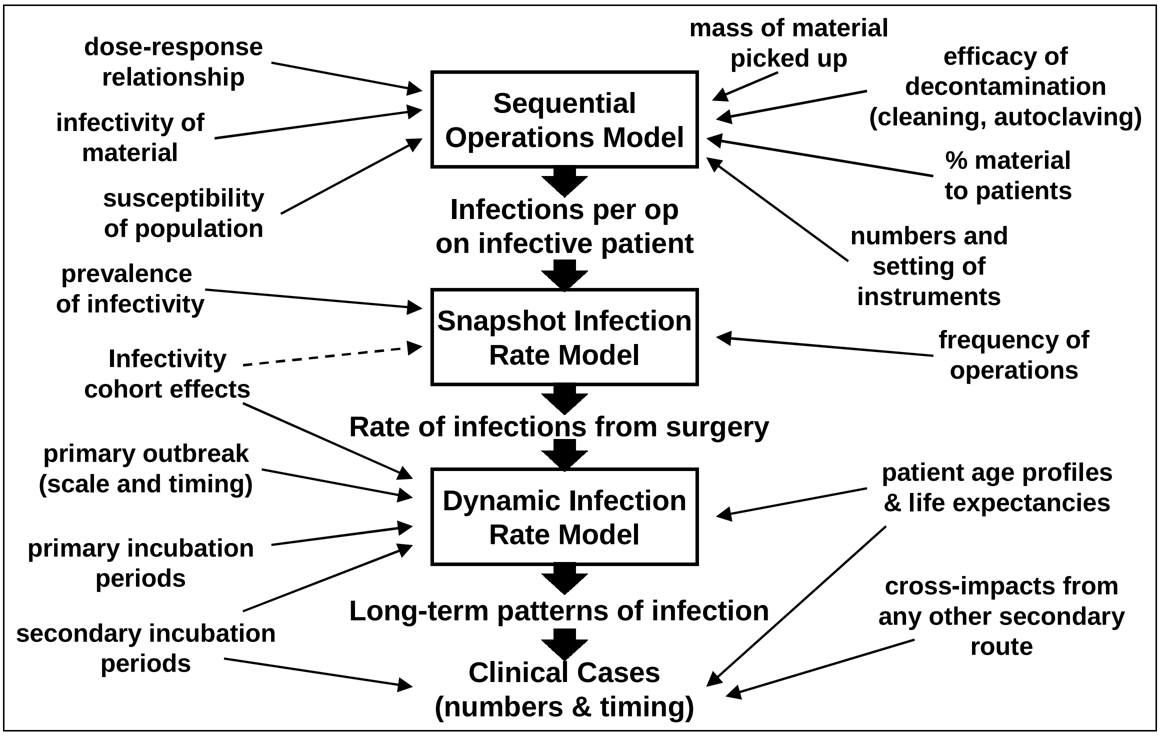

Figure 4: Summary of model parameters

Figure 5 shows the processes of the Sequential Operations model developed in the spreadsheet and subsequently implemented in the system dynamics model. Each operation using the instruments after they have been used on an infective person results in a new cycle of cleaning and decontamination resulting is less infective material left for each subsequent patient. Material transferred from an instrument to patient also reduces the amount that can be transferred to subsequent patients. Whether instruments are maintained in sets or separated out into different sets also impacts whether a single patient is exposed to multiple infected instruments in the next stage of use, or whether multiple patients are exposed to single instruments.

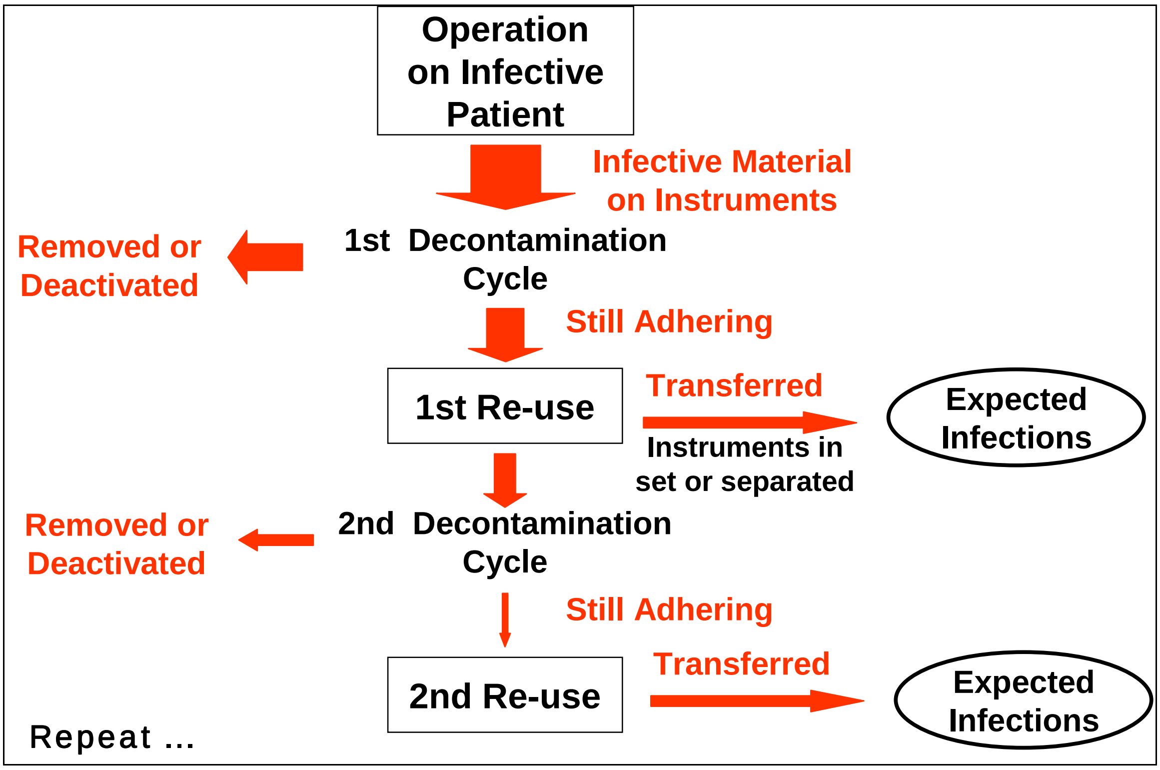

Figure 5: Structure of the Sequential Operations model

The system dynamics model contains an implementation the Sequential Operations model (the Instruments module) and a representation of the population states with regard to the disease (the Population module). The Surgical module provides the link between the two, representing the rate of operations. The prevalence of infected people who are unknown to be infected impacts the rate at which instruments will be come infected, and the various characteristics of the Sequential Operations model determines the rate at which previously uninfected people become infected.

Figure 6 shows a high-level view of the Population module. While the details in the module cannot be seen from the figure, it provides a map, with labels, of the main concepts in the module. The Susceptible Population represents the pool of people who have not been infected through either primary or secondary infection and are therefore susceptible to being infected through operations.

The Primary Infective Population are those people who were infected through primary causes (likely to be infected beef). The rate of infection of this group is specified as a time-series input. The Secondary Infective Population are those people infected through surgical instruments and also includes a time-series rate for other sources of secondary infection.

Both Primary and Secondary Infective Populations follow a similar structure. Each is split into two parallel groups – those who are confirmed as infective (and therefore do not present a risk for infecting others) and those who are unknown as infective and therefore do present a risk. Disease progression is represented as a five-stage process before symptoms show and then a final clinical stage where symptoms are apparent and lead to death. First order delays are used for the flow rates between each stage. Best clinical advice suggests that the incubation time follows an Erlang 5 (5^{th} order) distribution. Separating these out into five distinct stages allows flows to be added for movement from the unknown to the confirmed group and also rates out for death from other causes.

The population model also includes birth rates (into the Susceptible pool) and death rates from all of the pools.

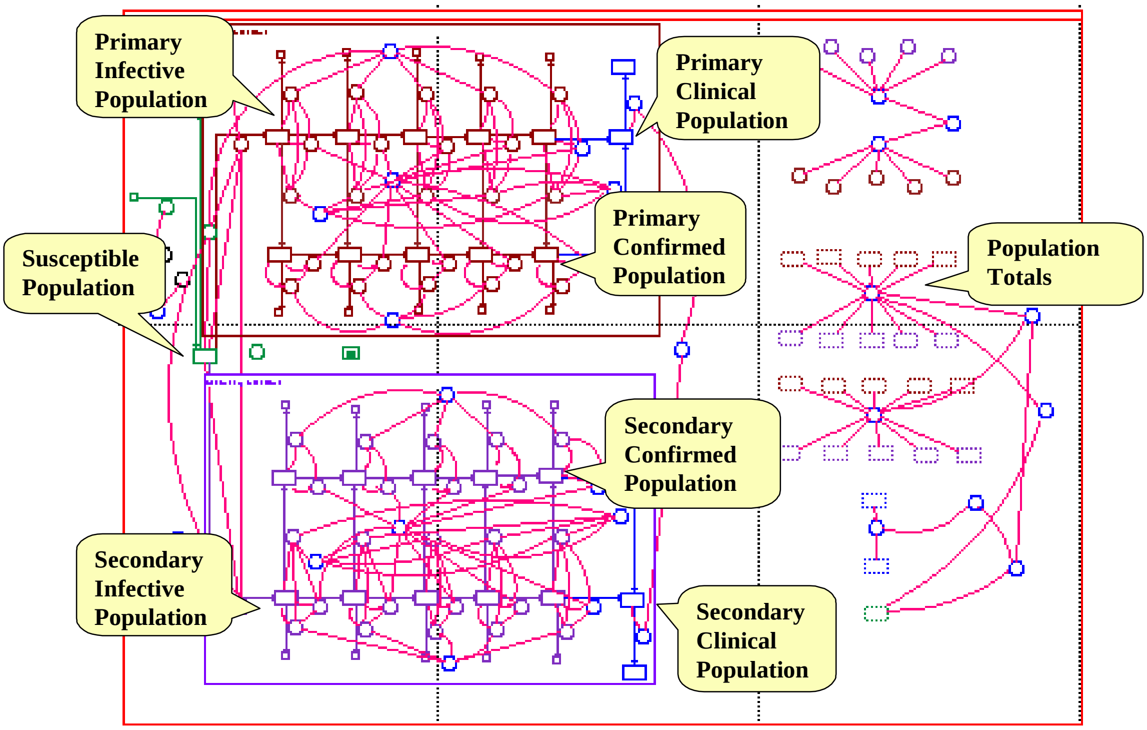

Figure 6: The Population module

A high level view of the Instrument module is shown in Figure 7. This is an implementation of the Sequential Operation Model. This represents eight steps of re-use of the instruments after infection. Eight steps was found to be the maximum number of steps required for a significant impact on infection rates for feasible values of the parameters. At the eighth step, all material still adhering to the instrument is assumed to be passed to that patient so that the model will, if anything, over-estimate rather than under-estimate the risk.

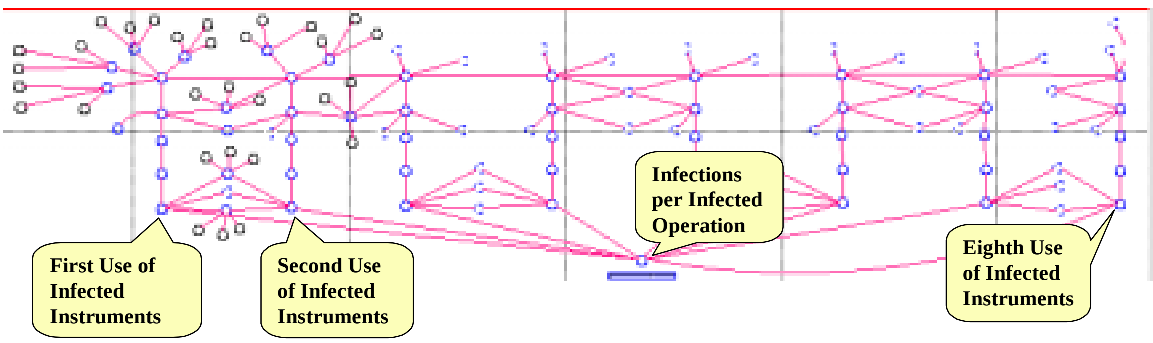

Figure 7: The Instruments module

Figure 8 shows a high level view of the Surgical module. This represents the rate of operations and the subsequent rate of infection of instruments. Also included in the module is a representation of patient screening with a likelihood detecting the disease. Detection of the disease prevents the instruments used on that patient from infecting other people and also moves people from the unknown to the confirmed group.

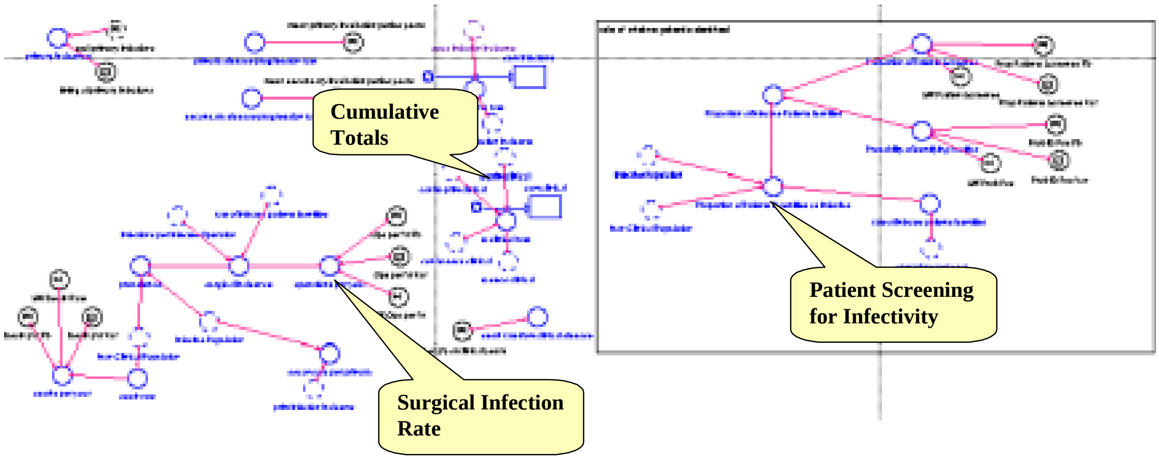

Figure 8: The Surgical module

Stage 4 System Dynamics Model Details

The Stage 4 system dynamics model was a further development of the previous model that replaced the Instruments module, based on the spreadsheet Sequential Operations Model, with a systemic representation of the population of surgical instruments. An overview of the Instrument Population module is shown in Figure 9.

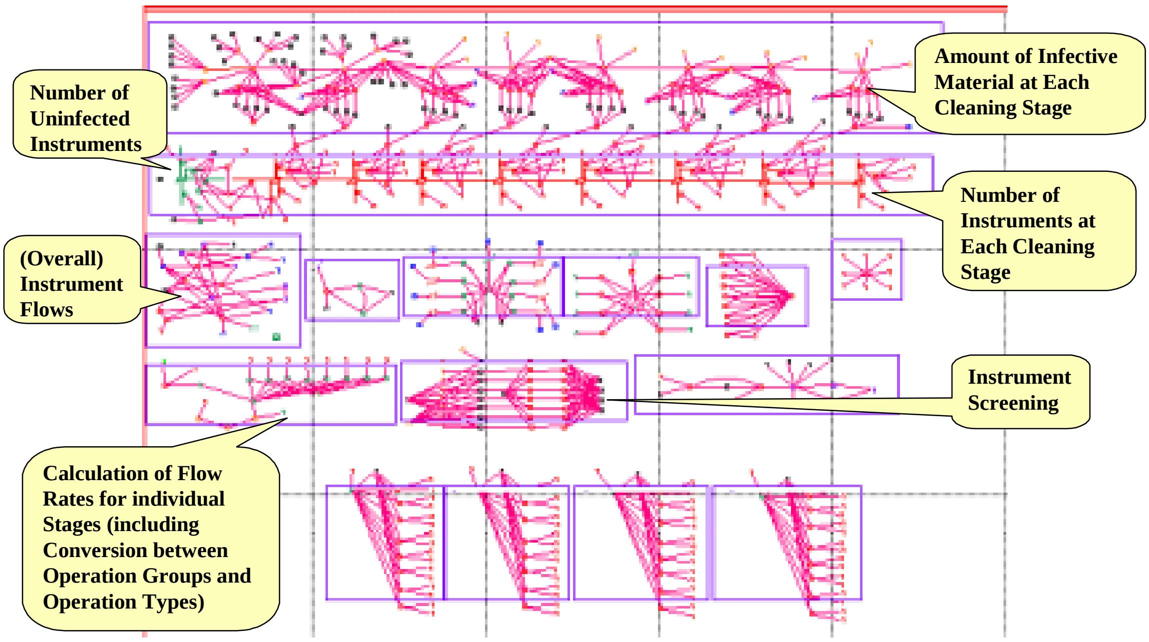

Figure 9: The Instrument Population module

The Instrument Population module allows a more detailed representation of the instruments, including arraying by instrument type to represent different characteristics of adherence of material and cleaning, and arraying by operation type with different levels of cross infectivity. The mechanism allows specification of which instruments types are used for the different types of operation, and for setting policies on restricting use of instruments to within certain groups of operation. In addition, introduction of new instruments and destruction of others allows the representation of single-use instruments and instrument life-span.

The Instrument Population module allows a representation of instrument screening for identification of infected material. In addition the systemic approach also corrects some minor over-counting by the Sequential Operations Model by representing the re-infection of instruments before they have gone through all of the steps of re-use.

The 4th Stage system dynamics model allows detailed examination of questions and policies that go beyond the scope of the study that was in progress but was felt to be valuable for looking at further questions in later studies. The data requirements for the model are also significantly higher for the 4th Stage model, although the arraying for instrument and operation types is flexible such that the number of categories can be chosen so as to be suitable for the nature of the study.

The added complexity of the data and relationships was such that a spreadsheet was required for data handling rather than the native user-interface of the software. The front sheet of the user interface is shown in Figure 10, and provides an overview of the data sectors that are used.

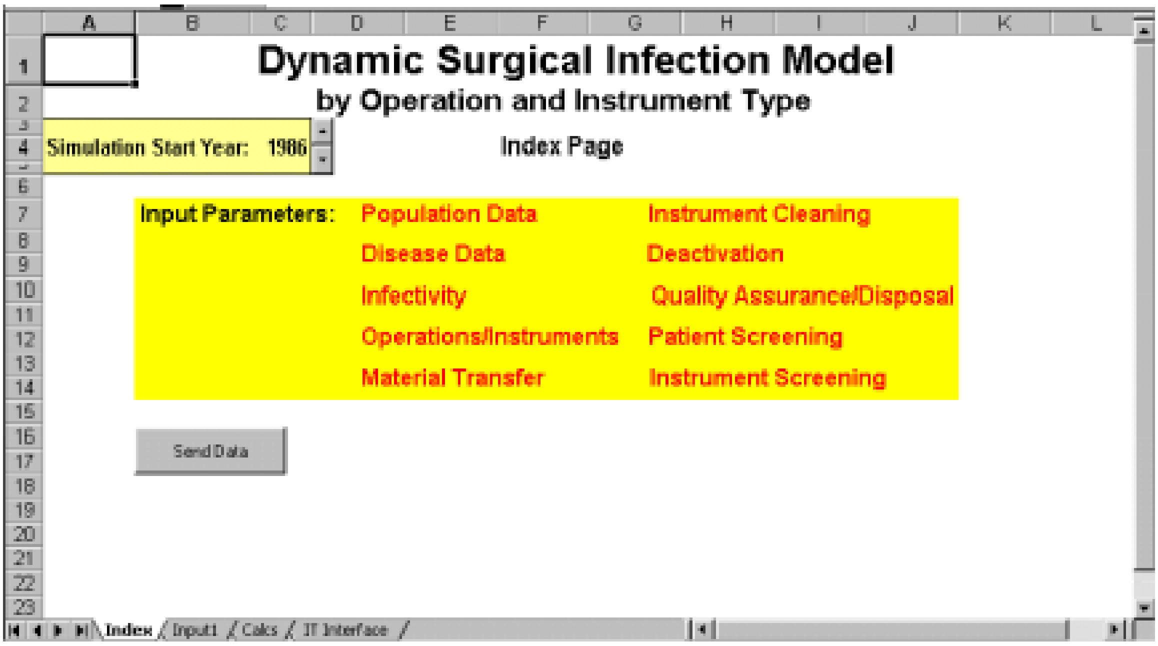

Figure 10: Front sheet of the user interface

Conclusions

This paper has provided an overview into the model building process and key structural elements of the resulting models. The conclusions from the Department of Health study are outside the scope of this paper, but can be read in the Department of Health report which is in the public domain.

Review of the model building process has led to the following conclusions and lessons learned.

- Static models provided a good insight into risks from use of infected surgical instrument, while the system dynamics model (Stage 3) adds a time dimension for changing population characteristics and impact of policy timing.

- The system dynamics model allows a long-term view, with investigation of the circumstances in which vCJD could become endemic in the population.

- The development process shows how static spreadsheet models can help in the construction of system dynamics models (or vice versa).

- Carefully staged development of system dynamics models allows production of models with different study aims and data requirements, with minimal cost and time overheads.

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