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Virtual patients as a practical realisation of the e-learning idea in medicine

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1. Introduction

Medicine has long been regarded as a discipline impossible to teach online. The complexity of the human organism and the intricacies of the patient-doctor interaction seemed beyond the reach of 'soulless' computers. However, a brief glimpse at recent advances in medical education reveals a different picture. The technically savvy Generation Y has entered medical school and their expectations of learning methods are different from previous generations'. Electronic devices like laptops, palmtops and smartphones are no longer expensive gimmicks, but have become indispensable elements of everyday life. This evolution coincides with significant changes in the healthcare sector. The ageing population demands increasing attention from medical personnel, resulting in a reduction in the time that can be devoted to teaching activities. In addition, the trend towards decreasing lengths of patients' stays in hospitals reduces the possibilities for medical students to observe the treatment process. It is in this context that harnessing computers to support the learning process by simulation of clinical scenarios may be very helpful, especially in the case of rare conditions.

Virtual patients (VPs) are "interactive computer simulations of real-life clinical scenarios for the purpose of medical training, education, or assessment" (Ellaway et al., 2006b). They offer a wide variety of (anonymous) patient-related data including medical history, physical and technical examinations, as well as laboratory tests. In most cases, the goal of the student is to find the right diagnosis and propose a correct medical treatment based on the data presented. Virtual patients provide a training opportunity in a risk-free environment before students are allowed to take part in bedside teaching. They may also be used to document the fact that all students have been exposed to all diseases defined by curricular objectives. The first virtual patient systems emerged in the early 70's (Harless et al., 1971) and since then have evolved significantly, taking advantage of new possibilities offered by the Internet and multimedia technologies. Research has shown that such systems enable students to learn clinical problem-solving more efficiently (Lyon et al., 1992). Increasingly,

more and more medical schools are utilising virtual patients and indeed embedding them into their curricula.

As is often the case with new terms their meaning may vary in the community, which sometimes leads to misunderstandings. For that reason it is imperative to differentiate between the definition of a virtual patient as presented in this chapter and related concepts. Most virtual patients are entirely computer-based and should not be confused with standardised patients – i.e. human actors playing the role of patients (Barrows, 1993), nor with high-fidelity computer simulators connected to realistic robot mannequins (Bradley, 2006). However, some learning scenarios use a combination of these techniques. Also beyond the scope of this chapter are computer simulations of biological processes for research purposes, and electronic versions of patient health records created for medical documentation (Ellaway, 2004). Virtual patients consist of a set of patient-related medical data that can be organised in various forms, thereby allowing its division into different classes of systems. In linear systems the information is displayed in a fixed, predefined order. A user's decisions do not have an influence on how a case unfolds. Such cases can be created, for instance in the virtual patient system CASUS® (Figure 1) (Fischer, 2000).

Branched systems offer the students various paths to the solution of a case. The user is confronted with a clinical situation and may select one from a set of options. The user's decisions affect the treatment of the patient, which may in turn result in different outcomes. The underlying model of this virtual patient class is a directed graph with nodes presenting the current status of the patient, while the edges visualise the possible transitions between states. A model of a branched virtual patient is presented in Figure 2. A good example of a system from the class of branched models is Open Labyrinth (WWW_12).

Template-based systems (e.g. CAMPUS (Garde et al., 2007) or Web-SP (Zary et al., 2006)) offer students a very wide choice of possible options. The user may select from hundreds of interview questions, laboratory exams, physical examination and treatment methods. Most options contain standard values, but some have been changed manually by the case's author to reflect the characteristics of the condition in question. Many pre-built templates use standardised terminology, which assures high quality and completeness of the data. The core of virtual patients may also be implemented as a complex mathematical model enabling the simulation of physiological regulations such as renal function, respiration or body-fluid balance. The system GOLEM devised at Charles University in Prague is a set of nearly 40 non-linear differential and algebraic functions that describe almost 200 input and output variables (Kofránek et al., 2003). Using GOLEM allows many different clinical scenarios to be simulated (e.g. circulation insufficiency, renal disorders, diarrhoea). This enables students to learn by experimenting with the basics of physiology. Knowledge-based virtual patient systems (e.g. Docs'n Drug or D3 WebTrain) are created dynamically from declarative data by means of a knowledge interpreter (Holzer et al., 2005). A recent trend in the authoring of virtual patients is to embed them as 3D-characters in virtual worlds, like for example, Second Life (Conradi et al., 2009). In such an environment the user may work on the cases collaboratively with fellow students through the Internet. Margaret Bearman (Bearman & Cesnik, 2001)(Bearman et al., 2001) attempts to summarise the variety of virtual patient models by dividing them into two major groups: problem-solving and narrative models. In the former a student has to deal with a large set of raw information and has to decide by himself what is relevant. In the latter, a patient's personal storyline is presented. The first model allows more freedom in information collection, whereas the second

encourages reflective learning through experience gained in observing the correct medical treatment patterns.

Fig. 1. Linear VP system – CASUS®

The introduction of virtual patients offers several advantages in comparison to the traditional methods of teaching clinical skills. The learning materials, following the e-learning paradigm, are accessible anytime and from almost anywhere. Once available they potentially require fewer personnel and resources to conduct the courses, depending on the level of integration with face-to-face teaching. They may help in solving some of the ethical problems arising with bedside teaching. Mistakes made by students have no significant consequences, which enables less stressful learning. Situations that involve strong emotions (like breaking bad news or dealing with violent, aggressive patients) may be practised in a safe-environment. Fewer students in operation theatres or clinics also reduce the danger of hospital infections. Virtual patients are more standardised in teaching than human actors and may convey a significantly higher amount of didactic information (Triola et al., 2006). The knowledge presented by these systems can also be rapidly updated when it is necessary to do so. Additionally, multimedia presentations, combining images, animations, video and audio clips are more stimulating than plain books, thus contributing to more efficient learning (Prensky, 2001). It has been demonstrated that virtual patient systems can be used to foster not only the learning of clinical and bioethical decision making, but also basic doctor-patient communication and history taking (Kenny et al., 2007)(Stevens et al., 2006). Nevertheless, it is imperative to acknowledge that artificial models are not equivalent to encountering real patients and cannot entirely replace traditional bedside teaching. Modern state-of-the-art simulations are still a long way from the realism of symptoms exhibited by real world patients. Learning at home using virtual patients requires a lot of self-discipline and motivation, which is not always given. Deterioration in enthusiasm for learning can also be caused by a lack of personal face-to-face feedback from the tutor and easy interaction with fellow students. Computers connected to the Internet tempt users with the wealth of

distractions available online (as is also the case in other branches of e-learning). The current design of curricula in many medical schools makes it difficult to align the virtual patients properly with other didactic activities. A lack of computer skills and difficulties in accessing broadband Internet connections are sometimes still a hindrance.

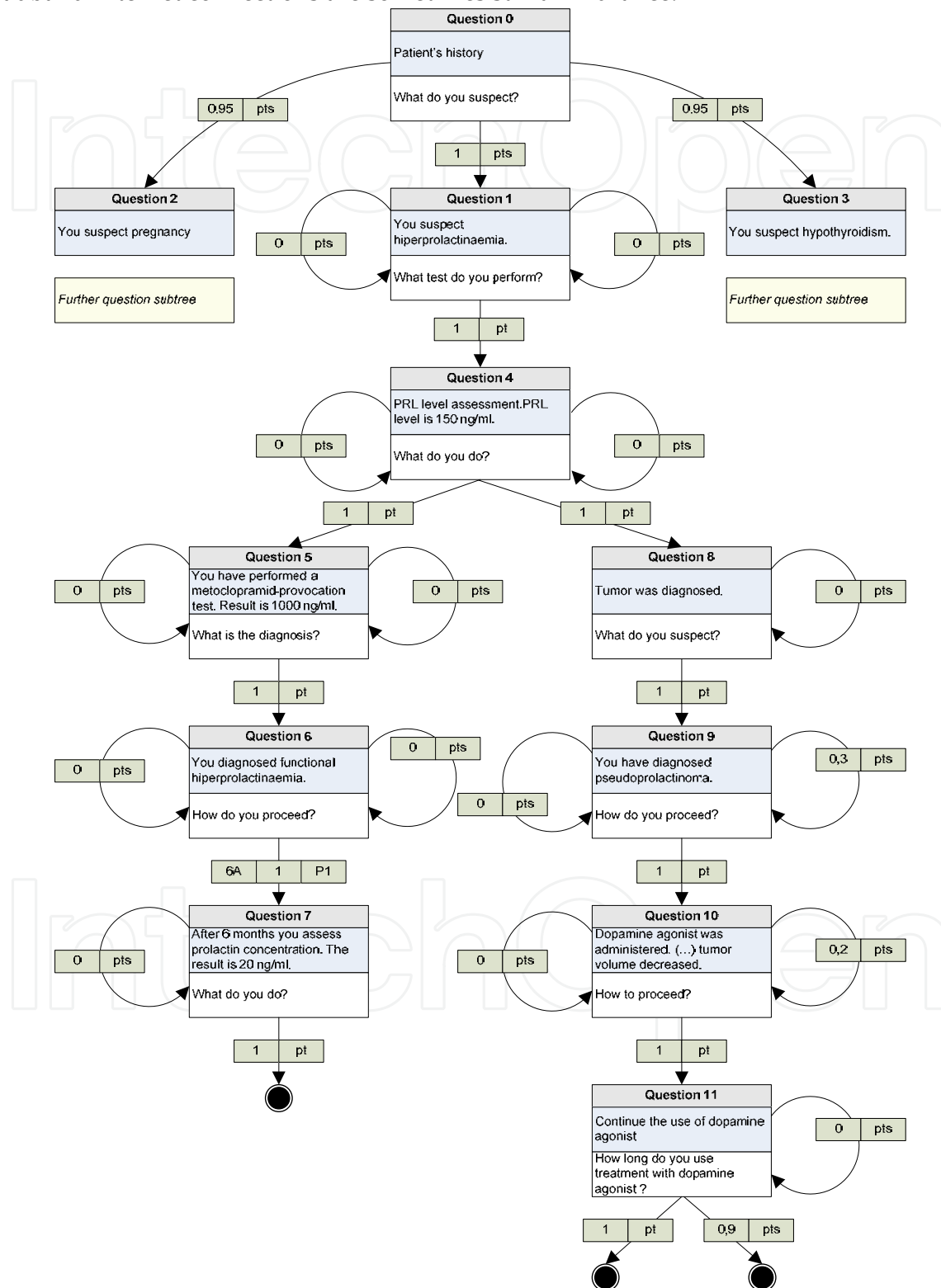


Fig. 2. Fragment of a branched model of a VP (simplified) (Kononowicz et al., 2005)

It is hard to decide which type of virtual patient is the best. The answer depends on many factors - e.g. learning objectives, concrete implementation of the model, applied learning scenarios. Our experience includes active development of virtual patient systems and participation in creation of their educational content in both linear (CASUS® (Fischer, 2000), (Hege et al., 2009)) and branched models (BIT Exam (Kononowicz et al., 2005)). Thanks to the participation in the European project eViP (→ section 7) we have also learnt in practice the usage of template-based systems such as CAMPUS or Web-SP. Each model has its strength and weaknesses. Based on our experience, we may conclude that linear models tend to be easier to implement and explain to content matter experts than branched. More than 1000 cases have been created within the CASUS® system and deployed at various universities around the world, whereas the usage of branched systems is, so far, less propagated. On the other hand linear models do not give students the freedom of choices they have in clinical practice. It seems more difficult to show realistically the consequences of actions in linear models than in branched. Template-based systems provide the learners with an abundance of choices but due to limited guidance they may not be an optimal choice for novice students, but more suitable for continuing medical education (CME). However, all of the above mentioned issues need to be formally tested by studies higher up the Kirkpatrick's levels of training evaluation (Kirkpatrick, 1998). This requires large scale and long term multi-centred studies that hopefully will be conducted in the coming years.

2. Virtual Patient Systems

Most virtual patient systems include a player, authoring tool, administration component, storage system, indexing facilities and assessment tools, all of which will be described in more detail in the following section.

2.1 VP Players

Virtual patient players are applications for displaying the content of patient cases. The player decides how the medical data should be presented to the student and how the user may interact with the system. Virtual patient systems exist which offer alternative players presenting the same underlying content in various ways (e.g. the CAMPUS system offers a resource intensive Classic Player and a fast, light-weight Card Player (WWW_02)). According to a survey by Huang et al. (Huang et al., 2007) most of the virtual patient players require an Internet connection. Offline VP courses distributed via CD-ROM and DVD-ROM have gradually been replaced by web applications running in generic web browsers. This trend can be easily explained by the advantages offered by fast updates to the content which are possible in centralised server-based installations. The disadvantages of web solutions, such as latencies in the transmission of multimedia rich content are compensated for by the increase in bandwidth of Internet connections and optimised media codecs.

Navigation in VP players most commonly involves selection of options with the mouse pointer. Depending on the data model, the case unfolds linearly or branches according to student choices. However, there are also players which are navigated by natural language recognition (Bergin & Fors, 2003). The learner types in questions to the virtual patient, orders medical examinations or therapy activities, and the systems tries to respond accordingly. The most technically advanced systems go even further by offering speech

recognition (Kenny et al., 2007) or even analysis of a student's movements and gestures by video cameras (Stevens et al., 2006).

M-learning is a recent trend in distance learning which aims to miniaturise devices used for displaying educational content. This approach is also found in the design of virtual patient players, of which the first pilot projects are currently being implemented. In Figure 3 two prototypes are presented. The first one displays virtual patients in a generic web browser on a palmtop, but modified by XSLT transformation to fit the size of a small portable device. The second example shows a VP player implemented as a J2ME Midlet.



Fig. 3. Virtual patient players on mobile devices for palmtop and mobile phones (Kononowicz, Pękała, unpublished) – pilot project

The majority of publicly available virtual patient players only support content that conforms to the VP system's proprietary data model (Holzer et al., 2005). The attempts to build a generic VP player have not been very successful so far. However, new hope for a common solution that will facilitate interoperability between VP systems has been raised by the introduction of the MedBiquitous' MVP standard (→ section 5) (Smothers & Azan, 2008). A profile of this standard has been implemented by four systems used in the eViP project (→ section 7).

2.2 VP Authoring Tools

Virtual patient authoring tools are software components required for the creation of new content, or modifications to existing cases. The authoring tool usually reflects the characteristics of individual VP models. The goal often striven for is to design the authoring environment in a way that would enable a medical subject matter expert to construct and modify the core features of the virtual patient single-handedly without advanced IT skills. A good example of an easy to use authoring environment is provided by the CASUS® system (Figure 4).

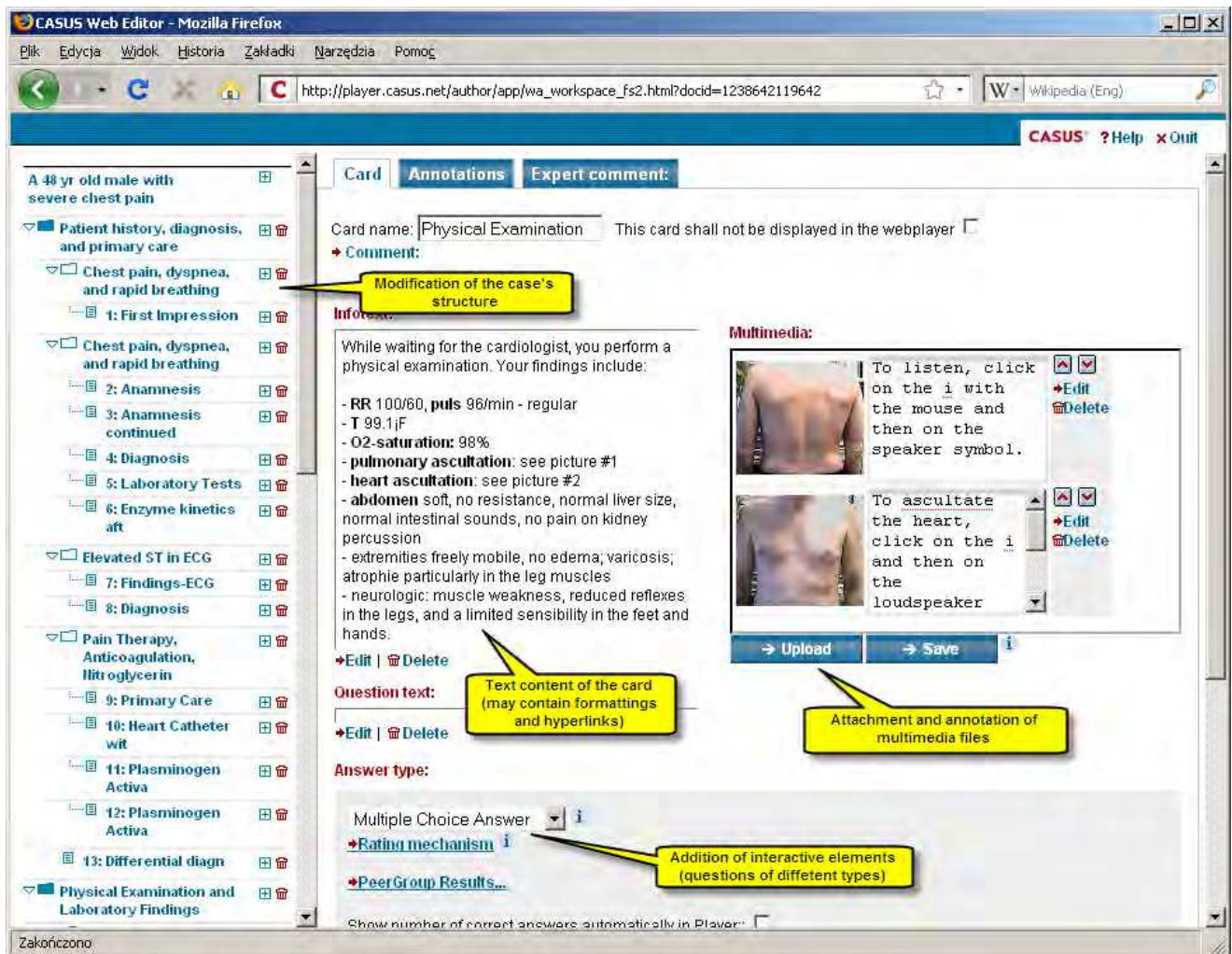


Fig. 4. Authoring environment of the CASUS® system

Operated by a standard web browser, it enables the authoring of cases from different locations without additional software installations. The simple linear structure is easily understood and supports fast development of cases. In the experience of one of the authors, post-graduate students who were assigned their own cases to create only required a quick 1-2 hour tutorial to sufficiently explain the basics of the tool, thus allowing the autonomous development of VPs.

External tools that were initially designed for other purposes are reused by some VP systems for the authoring of cases. A good example is the branched system Open Labyrinth utilised at St George's University of London. The graph-like structure of a case is designed in the Visual Understanding Environment (VUE) - an open source tool implemented at Tufts University (Kumar & Saigal, 2005). VUE facilitates the creation of conceptual maps of structured digital information. A map of a VP case developed in VUE is then imported into the Open Labyrinth environment for further processing (eViP's TRG, 2009).

2.3 Course Managers

Virtual patients are usually clustered into learning courses. Students are enrolled individually or in groups by tutors. More sophisticated solutions are based on federated identity-based authentication and authorisation infrastructure (AAI), which enables single sign-on (SSO) access to all e-learning services (e.g. SwitchAAI (Hämmerle, 2006)). Access to virtual patients should be protected for patient privacy reasons (→ section 6). Grouping patients into courses facilitates the fulfilment of didactic goals. An instructor may guide students along the recommended learning path by controlling the timing of virtual patient availability. Individual tutors and administrators may also be assigned to courses, thus helping to assure the scalability of the system.

2.4 Student Assessment Tools

One potential use of virtual patients is in student assessment (→ section 5). A role of virtual patient systems is to provide the teacher with an insight into students' activity in the learning module. Parameters such as login time and count, session length, percentage of visited content, answers given and their correctness are often monitored. One advantage of exporting the results into a universal format (e.g. CSV, Excel) is that it enables complex analysis of the results in external statistical packages, which in turn facilitates research into the effectiveness of virtual patients in teaching.

2.5 Reviews/Evaluation

High quality virtual patient content is a prerequisite to achieving good learning results. Virtual patient systems often incorporate internal or external evaluation tools; both for subject matter experts who review the content, as well as for end-users learning from the resources. Evaluation questionnaires, as developed by the eViP consortium (de Leng et al., 2009), (Huwendiek et al., 2009) are usually offered to students at the end of a case. They can be very tightly integrated with the VP system (e.g. in CASUS system) or be handled by external survey tools integrated with the evaluation.

2.6 VP Repositories and Referatories

Virtual patients can be disseminated by repositories and referatories. Repositories are electronic catalogues containing virtual patient packages that can be reused. Referatories, on the other hand, are collections of metadata describing the cases. They may contain information about the condition, learning objectives, licence agreements and prerequisite knowledge needed to solve the case, but do not actually contain the educational resource. For instance the eViP consortium creates their own referatory of cases which collects metadata regarding virtual patients published and repurposed within the project. Both institutions of the chapter authors contribute actively in the project by reporting their work in the referatory.

The presented overview of different types of tools available in virtual patients systems gives an insight into the diversity of functions required for virtual patient usage. There is a constant need for adding improvements in the already presented tools. However, while developing new or upgrading existing tools, backward compatibility to existing systems, which already have been well integrated into the curriculum, cannot be forgotten.

3. Virtual patient authoring

In this section we will highlight the didactical and medical steps which are important for the creation of virtual patients and a virtual patient curriculum.

3.1 Preparatory steps

In their article "A practical guide to developing effective web-based learning", Cook et al define four important steps which must be carried out before commencing with VP creation (Cook & Dupras, 2004). Although focused on web-based medical education courses, most of the steps apply to all kinds of VPs.

As a first step they recommend a needs assessment to identify problems and learners' and educators' needs. It is also recommended to think about the educational scenario in which the VP will be integrated. For example it could be used in a problem-oriented learning (POL) seminar, as a self-directed learning unit or for assessment (see next section for further information). This also determines the approximate length or learning time of the VP.

Steps 2 and 3 focus on determining the technical resources and needs of both educators and students. It is important to choose an appropriate learning system, which best meets the requirements defined in step 1. Most often the system already implemented at the local institution is used, but as seen in section 1 and 2 of this chapter there are numerous systems with different educational approaches already available. Related to this aspect is the choice of the VP model as described in the introduction.

In step 4 the commitment of all potentially involved staff and learners should be secured and potential barriers identified. Greenalgh suggests a team-based multidisciplinary approach as a successful model and emphasises the importance of incentives and rewards for all actively involved staff (Greenalgh, 2001).

3.2 Metadata definition

For the authoring of a virtual patient it is recommended to define educational metadata which includes learning objectives. The topic of a VP could be either a relevant disease which should be taught using a VP before a real patient is encountered, or a more exotic disease which is unlikely to be seen in a real patient.

As recommended by Fall et al (Fall et al., 2005), a crucial preparatory step before starting the creation of a VP is the definition of the clearly written learning objectives it should deliver. Cook et al. not only recommend concentrating on medical knowledge, but also on the skills and attitudes which the VP is designed to engender (part of step 1) (Cook et al., 2004).

A very good definition of a learning objective is given by Mager:

"An objective is a description of performance you want learners to be able to exhibit before you consider them competent. An objective describes an intended result of instruction, rather than the process of instruction itself." (Mager, 1962) and the Mager model (Mager, 1975). This model recommends that learning objectives should fulfil the following three requirements:

- should have a measurable verb (e.g. "explain", "demonstrate", "define", instead of "know")
- should give a specification about what the learners are taught

- criteria for success and competence shall be defined.

There are also numerous learning objectives catalogues which can be used as guidelines, for example the Swiss Catalogue of Learning Objectives (Bloch & Burgin, 2002) or the Objectives for the Qualifying Examination published by the Medical Council of Canada (WWW_11).

The target group is an important piece of metadata to define, because this has a major impact on the level of difficulty of the VP. Possible target groups are, for example, undergraduate medical students (pre-clinical, first year, final year, etc), interns and residents (continuing medical education - CME), nurses or physiotherapists.

3.3 Creation approach

When collecting material for the creation of VPs, there are three approaches used independently from the learning system:

- Taking a real patient's history and use his/her findings as base for the VP (e.g. implemented in the CASEPORT project (Holzer et al., 2005))
- Invent a patient history and collect/create all relevant findings (e.g. implemented in the CLIPP project (WWW_04))
- Repurpose an existing VP and adapt and enrich it to the curricular needs (e.g. implemented in the eViP project (WWW_06))

Of course for all approaches the copyright and patients consent aspects have to be considered (→ section 6).

For the first and the third approach the patient history might need to be adapted or reduced to match the learning objectives which are to be achieved by the VP. Using the second approach the continuity of the VP has to be considered (e.g. when collecting findings - especially images - the age, gender of the patient has to match!). Using the third approach can save time and money, if there is a VP which already meets most of the aspects defined previously.

3.4 Writing a VP

It is recommended by Fall et al. that a multi-institutional approach is used for creating VPs or VP curriculum, especially when they are to be distributed to other institutions other than your own. This enhances the applicability of these VPs at other institutions (Fall et al., 2005). Although most of the VP systems offer an authoring system to enter VPs easily, there are also other possibilities to consider. For example the CLIPP project uses a word processor template for the authors to enter their VP which was transferred into a VP system after the final expert review. This offers authors the option to working offline, and no system-specific training is necessary. Using a wiki could be useful for a shared VP creation with more than one author.

Concerning the "real" text creation for the VP there are some aspects to consider.

- Use first or second person narrative wherever possible to directly engage the learner (Clark & Mayer, 2003).

- Multimedia can significantly increase the effectiveness of the VP (Marinopoulos et al., 2007) provided it is essential to the learning process and not just decorative (Masters & Ellaway, 2008).
- Include interactions in the form of quizzes, self-assessment or interaction with other participants is crucial (WWW_04).
- Consider the needs of students with disabilities. A good starting point for more information is the website of Equal Access to Software and Information (<http://people.rit.edu/easi>).
- Include evidence-based key-teaching points and references (Fall et al., 2005).
- For the linear model the structure of the VP is typically standard history, examination, investigation, diagnosis, treatment (HxExIxDxTx) (Ellaway et al., 2008).

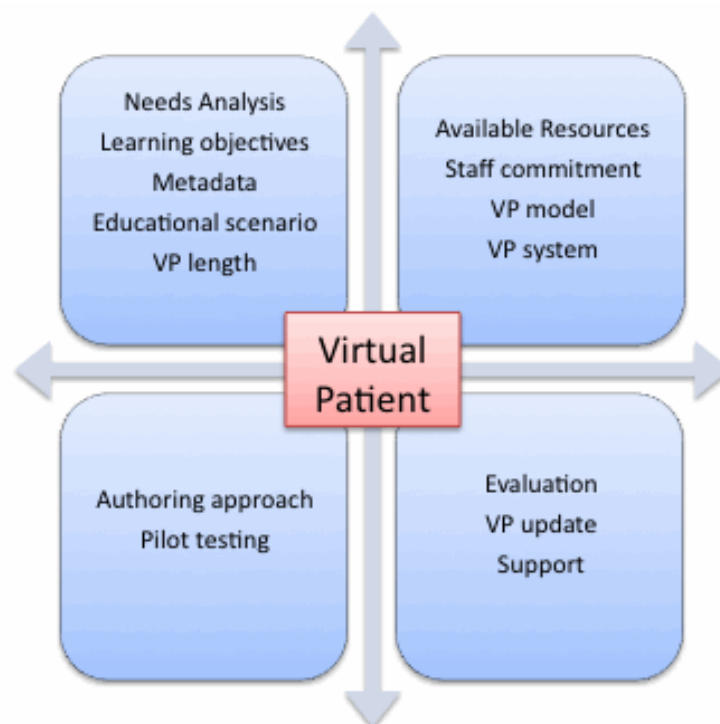


Fig. 5. Steps involved in the creation of a VP

3.5 Amount of time and money

A survey conducted by Huang et al. including 142 medical schools found that one third of virtual patients cost more than \$50,000 and 80% cost more than \$10,000. The median production time was 17 months (Huang et al., 2007). As an example, the CLIPP project had an overall production time of 310 hours per VP (60 hours/VP for writing) with costs of about \$18,000/VP.

After having completed the VP creation, it is advised to have a content and didactic review.

Steps 8 to 10 suggested by Cook include the following:

- A formative and summative evaluation of the developed e-learning material should be planned (step 8). An evaluation during the integration period will give important feedback on the acceptance of the VP within the target group.
- Concerning implementation a pilot test among the target group of the developed material should be conducted (step 9). For example, a focus group can be used.
- Especially required time, how well the learning objectives have been covered, navigation and overall satisfaction should be evaluated.
- Step 10 recommends maintenance planning. This includes (depending on the chosen system course) moderation and monitoring, technical support, testing of external hyperlinks and, most importantly, the regular update of the content (Friedman, 1996).

Following similar guidelines more than 1000 virtual patient cases have been already developed or repurposed at the Ludwig-Maximilians-University in Munich or Jagiellonian University Medical College (e.g. in projects like NETWORK or eViP, → section 7).

4. VP implementation scenarios into the curriculum

An important issue which, as mentioned in section 3, should be considered before creating the VPs, is their integration into the curriculum. The integration strategy is a fundamental aspect of acceptance by learners.

As mentioned by Cook et. al. (Cook & Dupras, 2004) as step 7 of developing e-learning courses, it is not enough to assume that students will use offered e-learning resources without enhancing their participation. This is in line with many other studies (Hege et al., 2007), (Baumlin et al., 2000), (Cahill et al., 2002).

The three major aspects mentioned by Cook are the accessibility and user-friendliness of the system/website, the provision of extra time ("protected" time) for the learners to complete the course and the inclusion of a reward and/or consequences mechanism.

There are numerous methods for introducing VPs into a curriculum, each with its own pros and cons which will be highlighted briefly in the following section.

The easiest way is to make the VP available as a self-directed voluntary module without any specific strategy of reward. It could, for example, be used to compliment a face-to-face teaching unit. But, as mentioned above, without encouragement the participation of learners the use of the VP will be very low (Hege et al., 2007). Therefore, for example, Fischer et al recommend the proper integration of computer-based cases into a face-to-face learning curriculum in combination with the assessment framework (Fischer et al., 2005a).

Another option is the integration of VPs as an obligatory self-directed learning module. This is often applied in undergraduate curricula. Successful work with a VP can, for example, be mandatory for passing a course, but this extrinsic motivation of students does not necessarily lead to a thorough working through of the VP (Hege et al., 2007).

To foster a more intrinsic motivation of learners the offering of incentives is an option. Student acceptance can often be as high as for obligatory VPs when they are motivated by the relevance of the content to an exam (e.g. for an OSCE), or by the use of VPs as a preparatory tool for courses like seminars, tutorials or bedside-teaching. At the medical school of the LMU in Munich we have had very good experience implementing VPs in the curriculum in internal medicine as self-directed preparation for the weekly seminar (blended-learning approach) and introducing exam relevance of the VPs' content.

A different integration approach is Learning by Teaching (LBT) or a student authored approach, which means that one or more learners create a VP (or parts of it) as an educational activity (Ellaway et al, 2008), (Kononowicz et al., 2008). For instance postgraduate medical students at the Jagiellonian University Medical College create virtual patients as one of their assignments in the computer science seminar. Creating the clinical scenarios autonomously involves a deep understanding of the condition of the patient and didactic expertise. It is recommended that the VP creation is supported by an expert tutor. After expert review these VPs can be integrated into the curriculum as learning cases.

Apart from integrating VPs as single encounters, they can be included in a curriculum many times with a development over the time. This might be especially applicable for complex VPs (Ellaway et al, 2008).

Communication between learners is encouraged for several reasons. For example, Lou et al. found evidence that collaborative learning is a more effective way of learning (Lou et al., 2001). As mentioned by Valcke et al. research results suggest that adding a communication component like a discussion board to an information component like a VP results in better student performance (Valcke & De Wever, 2006).

Integrating VPs successfully into a curriculum often takes years. For example at the LMU VPs have been used for undergraduate medical education since 1993, but students' acceptance at the beginning was very low. Only after years could VPs be established as an integral component of the curriculum. Currently 15 VP courses (consisting of 5-15 VPs) in 13 different content domains are included in the curriculum in different educational settings.

4.1 Assessment using Virtual Patients

In recent years the introduction of virtual patients for assessment purposes has increased. Courteille et al. (Courteille et al., 2008) conducted a pilot study on using an interactive simulation of patients (ISP (Bergin & Fors, 2003)) for an OSCE-based exam. They showed that the VP could reliably differentiate between the performances of the students. An important prerequisite for successful integration is the training of students in mastering the exam tool. They also found a surprising influence on the students' performance by the human assistants.

At the University of Ulm an online assessment tool (OAT) on the basis of the virtual polyclinic "Docs'n drugs" was developed including three clinical scenarios implemented for an assessment study. They found a moderate correlation with written exams ($r=0.36$) and a higher correlation between the three scenarios ($r=0.50-0.56$) (Waldmann et al., 2008).

Even for the United States Medical Licensing Examination (USMLE) Step 3 examination a computer-based case simulation (CCS) has been introduced. Dillon et al. report on the research findings in this case. They conclude that CSS can be used for large-scale high-stakes testing and represents a unique contribution to the overall assessment of physicians, but the administration of such complex assessment formats is a challenge (Dillon et al., 2002).

Another implementation scenario is the key-feature approach (Bordage et al., 1995). A key-feature is defined as "a critical step in the resolution of a problem". Two corollaries were added by Page and Bordage: It focuses on a step in which examinees are most likely to make errors in the resolution of the problem, and it is a difficult aspect in of the identification and management of the problem in practice (Page & Bordage, 1995).

A study by Fischer et al. introduced a 15-item key feature exam for assessing clinical decision-making skills in undergraduate students (Fischer et al., 2005b). They found that

their modified key-feature exam (designed according to the guidelines provided by the Medical Council of Canada) was a reliable, valid and feasible method for assessing clinical decision making skills. The acceptance of students was intermediate and according to Fischer et al. could be improved by enhancing the curricular integration of such electronic case-studies.

5. Standards in virtual patients

Technical standards in e-learning establish norms which may help in achieving high quality content and foster the interoperability of educational resources. Since the development of virtual patients is expensive, standardisation efforts are in general very welcomed by the community. In order not to reinvent the wheel, standardisation bodies often reuse existing well-established specifications and extend them with new features characteristic for the given field of application. A keystone of many e-learning projects is the ADL SCORM (Sharable Content Object Reference Model) specification (WWW_01) which aggregates methods for describing the way learning resources may be packaged, structured and run in virtual learning environments.

A conceptual model for defining metadata of educational resources has been proposed in the IEEE 1484.12.1 Standard for Learning Object Metadata (LOM) (WWW_07). Having its representation in XML or RDF languages, the model presents a hierarchy of description items. Semantics of the leaf elements are defined by a branch of parental elements in the LOM description tree. The specification constrains the possible values of the items by defining permitted data types and controlled vocabularies. Allowing a high degree of flexibility in the usage of its elements, the standard supports the creation of its application profiles that represent the needs of individual communities.

The disadvantage of distributing virtual patients as generic SCORM sharable content objects with LOM metadata is the loss of descriptions characteristic for this kind of resource. A compromise between the adherence to well established standards and the addition of new features characteristic for medical education and VPs has been proposed by MedBiquitous. The MedBiquitous Consortium is a non-profit organisation aiming at establishing interoperability standards in healthcare education (Smother's et al., 2008b), (WWW_09). This organisation publishes profiled versions of well known e-learning specifications, such as IEEE LOM and SCORM, while also proposing new specifications e.g. for Activity Reporting and Medical Education Metrics. A particularly interesting proposal is the MedBiquitous' Virtual Patient (MVP) specification (Smother's & Azan, 2008a) which defines a format for exchanging case-based educational resources in medicine. Clinical and demographic data of a patient are saved in a Virtual Patient Data (VPD) document separately from the media resources (MR). A large set of predefined attributes characterising the virtual patient is defined, containing sections such as Medication, Interview Item, Physical Exam or Diagnosis. Media Resources are referenced in an IMS manifest file. The Data Availability Model aggregates both virtual patient data and media resources and makes them available for presentation in an order defined by the Activity Model (AM). The package's metadata can be expressed in Healthcare LOM - a profiled version of the IEEE Learning Object Metadata format. The MVP data is expected to be displayed in a run-time environment designed according to the MedBiquitous Virtual Patient Player specification (WWW_10). Figure 6 presents the relations between all elements of the MVP specification.

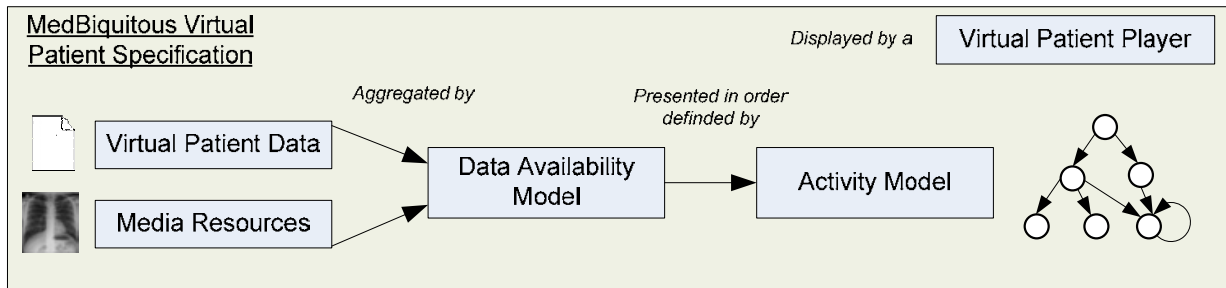


Fig. 6. Elements of the Mediquitous' Virtual Patient Specification

The MVP model has its binding in XML syntax. Together with files containing the Data Availability Model, Activity Model, Media Resources and metadata files, the content is inserted into a SCORM (IMS CP compliant) package which may be transferred between virtual patients systems. The Mediquitous' Virtual Patient Specification allows the exchange of VPs with different models including linear, branched or template-based types at different conformance levels (Kononowicz et al., 2009b). This has been successfully tested by the eViP project in which a profile of the MVP has been implemented in four VP systems (Zary et al., 2009). Unfortunately, due to high-level semantic differences, the import functionality still needs human intervention for some actions (e.g. while converting from branched to linear models).

There are also aspects of virtual patients which are not yet directly supported by the MVP specification. This applies, for instance, to question and assessment items which are frequently used by some VP systems (e.g. by CASUS). For such elements the use of external e-learning specifications is recommended (eViP's TRG, 2009). For instance, questions of various types may be easily implemented with the IMS Question and Test Interoperability (QTI) specification (WWW_08). This standard has been in development since 1999 and offers a data model for representing questions, tests and its results in a format that is independent of the authoring tool and assessment system. This enables storage of questions and their interchange regardless of the currently available e-learning infrastructure. Assessment items supported by the specification may be simple types (e.g. MCQ, MAQ, Sorting, Text Entry, Hot Spot, etc.) or be combined into more complex, customised types (i.e. composite items). The abstract QTI data model has its binding in XML syntax. The QTI specification is supported by many learning and assessment delivery systems (e.g. Moodle, Dokeos or Sakai). There are also implementations of this standard in VP systems (Pfähler & Holzer, 2009).

A further important problem that could be potentially solved by using standards is the integration of virtual patient systems with the existing e-learning infrastructure of universities (Holzer et al., 2005), (Kononowicz et al., 2009a). The SCORM Run-Time specification can be used to implement communication between a virtual learning environment (e.g. Blackboard or Moodle) and a virtual patient system. A Single Sign On (SSO) mechanism for various virtual patient tools can be implemented using Security Assertion Markup Language (SAML) implemented by the Shibboleth middleware (WWW_14). The Swiss Virtual Campus (SVC) is an example of an initiative aimed at the sharing of e-learning resources between Swiss universities (including medical faculties) via a federated identity-based authentication and authorisation infrastructure based on Shibboleth (SwitchAAI) (Hämmerle, 2006).

6. Intellectual property rights (IPR) and patient data safety in virtual patients (Miller et al., 2009)(WWW_15)

Intellectual property rights (IP) (WWW_16) are legal property rights over intellectual creations, such as books, movies, music, paintings, photographs, and software. Common types of intellectual property are, for example, copyrights, trademarks, patents and industrial design rights.

The IPR applicable in the context of virtual patients is copyright, which protects the expression of ideas or information. For a work to be protected by copyright, it has to be original and be expressed in a fixed material form, for example printed or electronically.

In Europe one does not have to register the copyright in the work before it is protected, but copyright is applied automatically. It gives the copyright holder the exclusive right to control the reproduction or adaptation of his work for a certain period of time.

The growing use and sharing of virtual patients in under- and postgraduate medical education increasingly brings into question the issue of how to protect digital content with the intention of it being shared among institutions, even worldwide. In the medical field apart from IPR issues there is the additional complexity of ensuring the patients' anonymity, since in most VPs clinical recordings such as images, x-rays or videos are included. If the patient-related data does not allow identification of the patient the media may be used without obtaining permission. However, due to advances in identification technology, and also because of the danger of missing a characteristic feature of the patient, it is always advised to get written consent from the patient.

To obtain permission from patients to use their personal medical information for a defined purpose a consent form is used. A considerable volume of litigation in many countries has focused on the issue of consent and as a consequence the doctrine of informed consent is assumed (Schachter & Fins, 2008).

Important initiatives to address these problems are described in the following section.

6.1 Creative commons (WWW_05)

Creative Commons (CC) is a non-Profit-Organisation, which develops and provides ready-made licensing contracts for the publication and distribution of digital media. CC is neither publisher nor contract partner of the copyright owners. For the simplest license the licensee only has to give the name of the grantor of the license. Modifications can be made depending whether commercial use is allowed or forbidden and whether edited versions can be distributed under the same conditions. This leads to six different licensing models with a combination of the following options:

- commercial/non-commercial use
- editing allowed/forbidden
- (no) redistribution under the same conditions

Which license form applies is clearly identifiable from the works' metadata, so normally there is no need for direct communication between creator and user. Despite its distinct advantages and overwhelming popularity, the CC is not ideal for sharing patient specific data in the form of digital content because it does not address the patient consent or

withdrawal of consent and the scope of permission (Miller et al., 2009). More information can be found on the CC website <http://www.creativecommons.org>.

6.2 The CHERRI project

The 'CHERRI' (Common Healthcare Educational Recordings Reusability Infrastructure - Practice, Interoperability and Ethics) project has carried out surveys in the UK of existing practice, researched the medico-legal context and developed a consent and licensing model that is anticipated to meet the needs of all those concerned (Ellaway et al., 2006).

The following problems were identified: "lack of common process and standards at institutions, lack of connection between terms of consent and subsequent use, unnecessary duplication in local contexts as a safety measure, and a pervading culture of risk and uncertainty that is leading to both individual and institutional anxiety and loss of utility". CHERRI has developed a conceptual Consent and Licensing Model that is based on the CC model and which addresses both the uncertainty and the disconnectedness of current practice.

Several recommendations have been published in the CHERRI report, including that all creators and users of clinical recordings for academic non-clinical settings should be better educated and supported in a normalised way for quality assurance reasons.

6.3 Report on the Management of Intellectual Property in Virtual Patients by the eViP project (Miller et al., 2009)

Any project aimed at sharing work across several jurisdictions faces the challenge of having a mutually accepted exchange system. In addition to considering existing works, this system must also clarify how to share works that are jointly created or repurposed.

The European project about Electronic Virtual patients (eViP) that is described in more detail in section 7 aims to enhance the sharing of VPs among European healthcare institutions. Since traditional ownership of content and jurisdiction differs in the participating countries a major challenge for the project has been to come to a common IPR and patient privacy agreement. The report on the management of IP in virtual patients addresses these different legal situations. Miller et al. found that although there are undoubtedly disparities between countries, measures can be adopted to prepare and protect digital information which is intended to be shared. The project has adopted a framework for a licensing model and outlines a five-step process for preparing and protecting digital content in the medical and healthcare area:

- Step 1: Review IP and copyright status in partner countries. Since Copyright is handled differently under each country's national laws and is regulated throughout Europe via a complex web of international conventions, treaties, agreements, and European Community (EC) Directives, a review of IP and copyright status was conducted for each partner country.

- Step 2: Compare copyright issues between partners to identify both, similarities and differences. Apart from many similarities in eViP partner countries, the main differences that have been found relate to duration and ownership of copyright. This shows that sharing copyright protected works among partner institutions is feasible.

- Step 3: Create a common consent form for recording patient information based on similarities between partnering countries which is compliant with national regulations and institutional policies. Such a form is a simple document establishing who may gain access to the information, the purpose of the study, an explanation of the uses, disclosures and what kind of teaching is involved. Within the eViP project a generic consent form has been created (Miller et al., 2009). The consent form has been translated into all partners' languages and reviewed by the legal departments of each partner's institutions.

- Step 4: Implement common consent. The eViP project came up with a model describing how this issue should be tackled. The clearance model which was devised is not just for signing off existing VP content, it is also meant as a best practice guideline to clear new content for medicine and healthcare. A problem arises if a patient's consent is not available for existing VP content, for example, because it was given orally, or does not cover its use within the intended project. To obtain new consent from that patient can be time-consuming or even impossible in some cases. The model, developed that the responsible clinician at the institution in question, should now evaluate the risk and decide whether to sign off the information. For this decision it is important to bear in mind the type, scope, quality and age of consent and the context in which it was obtained, and the value of the information and whether documentation exists. The advantage of this approach makes it less complex to decide how to handle valuable and difficult information, where otherwise the issues might not be addressed or the information discarded.

- Step 5: Adopt a simple and robust licensing model. Due to the limitations of CC concerning patients' consent and the scope of permission, the eViP project decided to develop an eViP common licensing model based on the current CC framework in cooperation with CCLearn [WWW_03].

Of course the results from the limited number of countries involved with eViP are not representative of jurisdictional differences or copyright laws throughout Europe. However, this process proved to be a very successful start in initiating and informing discussions with other countries, not just in the EU but also across the world. The process of introducing VPs at universities requires the support of the schools' leaders who need to clearly define the institutions' policies in creation and usage of these resources. Regulations regarding the ownership of the created cases, legal constraints in usage of patient-related data (consent form), possibilities for VP exchange, incentives for VP authors, the VP review process and a clear motivation for students to use VPs need to be thoroughly discussed. From our experience we have learned that such a process cannot be accomplished instantly but requires step-wise changes that can be introduced only in the course of a few years.

7. Virtual patient initiatives

As it has been pointed out in the third section of this chapter, the development process of virtual patients is expensive and time consuming. It involves collaboration of many technical and subject matter specialists, alignment of the content with the curriculum, as well as a thorough review by experts and evaluation by students. A possible solution to that shortcoming is to share the development costs among a group of institutions which would

then share the new resources. Rather than reinventing the wheel by duplicating existing resources, part of the work could be acquired from common databases. Some learning and virtual patient initiatives are presented below to give an overview of the projects contributing to the popularity of virtual patients. By analysing their experience, conclusions for future e-learning projects (also for types of resources other than virtual patients) may be drawn.

7.1 Digital libraries and catalogues

In the course of the past years millions of web pages have been published on-line. The value of resources varies considerably. In order to find something valuable just by a plain Google search the educator needs to waste lot of time on separating the “digital” wheat from the chaff. Even when appropriate content has been found, a lack of clarity in copyright clearance may often prevent the resource from being used. Fortunately, initiatives like the digital library MERLOT (McMartin, 2004) attempt to solve this problem by establishing large collections of free, peer-reviewed educational assets. The MERLOT (Multimedia Educational Resource for Learning and Online Teaching) initiative was launched in 1997 at the California State University Center for Distributed Learning and supports the sharing of learning materials from a large number of disciplines beyond health sciences (like business sciences, history, mathematics, physics, etc). However, there are also projects that focus explicitly on medical content. A good example is the HEAL (Health Education Assets Library) project initiated around 1998 by a consortium of American medical colleges (Candler et al., 2003). The database enables educators to search and retrieve digital multimedia objects and reuse them in, for instance, the authoring of virtual patients. The majority of the catalogued assets is peer-reviewed and indexed by relevant controlled vocabularies (like MeSH). After submitting a query a list of resources is displayed consisting of a thumbnail picture of the asset and a set of metadata. External collections of multimedia items can be attached on request to the central HEAL server. The MedEdPORTAL initiative also belongs to a group of peer-reviewed educational healthcare resource repositories (Reynolds & Candler, 2008). In the scope of this portal are larger assets than are usually available via HEAL. Single multimedia items are regarded in MedEdPortal as educationally incomplete and need to be extended by more detailed didactical instructions. The content does not necessarily need to be digitalised since paper-based learning materials are indexed as well. An interesting fact is that MedEdPortal host a large collection of references to over 80 virtual patients (AAMC Virtual Patient Collection), from well-known medical centres like Harvard Medical School, the University of Pittsburgh and New York University School of Medicine. The resources in the MedEdPORTAL are available on request under Creative Commons licences. The portal promotes the authoring of resource-intensive materials by facilitating scholar acknowledgement of the work. This includes the establishing of a strict peer review process (25% submissions rejected, 41% accepted with revisions) and a uniform citation mechanism.

7.2 eViP

Electronic Virtual Patients (eViP) is a project co-founded by the European Commission aimed at establishing a large collection of virtual patients (over 300 cases) from institutions across Europe (Balasubramaniam & Poulton, 2008) (WWW_06). The project started in 2007

and is planned to run for three years, but one of the project goals is to propose a sustainability model that will ensure the continuation of the database after the year 2010. Consisting of nine partner institutions from five countries: United Kingdom, Germany, Sweden, the Netherlands, Poland and Romania, the initiative guarantees that the content will be diverse in terms of the language and healthcare culture. Since the institutions are using four different virtual patient systems (CAMPUS, CASUS, Open Labyrinth and Web-SP) the resources need to be transferable between different data models. The shared resources are repurposed by the participating universities to enable the use of their content in the local conditions of the partner institutions (Stachoń et al., 2008). This involves translation of the content, and changes to reflect the characteristics of the national healthcare system and the medical curriculum. As part of this process the content is often additionally enriched by new medical data, media resources or formative assessment items. The problem of making the content transferable between different data models was solved by implementing the eViP application profile of the MedBiquitous Virtual Patient (MVP) specification (Zary et al., 2009). The quality of the import/export process is assessed by a four level conformance testing metrics (Kononowicz et al. 2009b) and may (to a certain level of semantic complexity) be tested automatically by software tools. The process of transferring content between institutions also touches upon patients' privacy and copyright issues, and these are examined by the project in the context of different legal systems (Miller et al., 2009). Finally, the project will evaluate the success of the introduction of the created and shared content into the curricula, but these results are not yet available at the moment of writing.

7.3 CLIPP

Clerkship directors from thirty northern American medical schools participated in the three year long programme Computer-assisted Learning in Paediatrics Project (CLIPP) (Fall et al., 2005). A set of 31 virtual patients covering all learning objectives published by the Council on Medical Student Education in Pediatrics (COMSEP) was developed, implemented on the CASUS platform and extensively tested. Currently about 100 medical schools in the U.S. and Canada have subscribed to use the paediatric curriculum of CLIPP with about 20,000 users per year. The price of a set of CLIPP cases pre user was approximately equal to a price of a text book which made the project economically reasonable. A further reuse of these resources will reduce this cost even more.

7.4 PREVIEW

The increasing popularity of online, multi-server virtual environments (MUVES) has encouraged educators to use them as platforms to engage students in e-learning. The most well known MUVE in use today is definitely Second Life (WWW_13). There are already many locations available in this environment specially destined for medical education (e.g. Healthinfo Island or VNEC) (Boulos et al., 2007). The enormous simulated world created by Second Life users also potentially provides a great opportunity to implement virtual patients. The goal of the PREVIEW project is to deliver problem-based learning scenarios in the world of Second Life (Conradi et al., 2009). A set of four PBL scenarios developed by St George's University of London for paramedic students uses virtual patients. Students - represented in the virtual environment by their avatars - work collectively on problem-

based sessions involving the administration of first aid in a street accident, as well as in life-endangering situations simulated in the underground and a night club. Provided with a paramedic equipment box, participants of such session may carry out various observations and examinations on virtual patients. An interesting feature of the PREVIEW's virtual patients is the fact that they are implemented following the MedBiquitous MVP standard. This in turn allows part of their content to be imported automatically from other virtual patient systems. Since learning in virtual worlds is gradually becoming more and more natural for the new generation of 'digital natives' (Prensky 2001), the way of presenting VPs demonstrated by the PREVIEW project may become increasingly important in the future.

7.5 Other projects

The selection of initiatives presented above shows the diversity of projects fostering virtual patient development. There are plenty of further programmes involving the usage of computerised case-based simulations in medicine that could not be described here in more detail. Worthy of attention are the European NETWORK project – a set of virtual patients in occupational medicine (Radon et al., 2006), REVIP – an Anglo-German project focussing on the embedding of repurposed and enriched Virtual Patients (VPs) within a Paediatrics curriculum (Balasubramaniam et al., 2009), CASEPORT – a national platform for virtual patients in Germany (Holzer et al., 2005) and the virtual patient collection managed by the International Virtual Medical School (IVIMEDS) (Harden & Hart, 2002), (Davies et al., 2006).

8. Summary

The goal of this chapter was to present the concept of virtual patients – i.e. computer-based simulations of clinical scenarios for educational purposes. Basic models and the technical aspects of both virtual patient creation and administration have been introduced, as well as standards for uniformly describing and sharing virtual patients. We have also touched briefly upon the underlying pedagogic concepts, including an overview of fundamental scenarios of virtual patient introduction into medical curricula. Since virtual patients deal with very sensitive data, the topic of patient consent and intellectual property rights in medical e-learning has also been discussed. This chapter has outlined many of the e-learning initiatives that have already emerged in supporting the creation and exchange of virtual patients. The outcomes of those initiatives give a valuable source of ideas on how to introduce virtual patients into educational settings successfully. Many aspects of virtual patients are relevant to case-based learning in general, including content domains outside of medicine and life sciences. We hope that some practical conclusions for non-medical e-learning applications can be drawn from this chapter. Despite their history, virtual patients are in many universities still poorly represented in curricula. We hope that our chapter will foster the usage of this learning method at medical schools.

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