A Decision Support System Based on Augmented Reality for the Safe Preparation of Chemotherapy Drugs

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Abstract. The preparation of chemotherapy drugs has always presented complex issues and challenges given the nature of the demand on the one hand, and the criticality of the treatments on the other. Chemotherapy involves handling special drugs that require specific precautions. These drugs are toxic and potentially harmful for people handling them. Their preparation entails therefore particular and complex procedures including preparation and control. The relevant control methods are often limited to the double visual control. The search for optimization and safety of pharmaco-technical processes leads to the use of new technologies with the main aim of improving patient care. In this respect, Augmented Reality (AR) technology can be an effective solution to support the control of chemotherapy preparations. It can be easily adapted to the chemotherapy drugs preparation environment. This paper introduces SmartPrep, an innovative decision support system (DSS) for the monitoring of chemotherapy drugs preparation. The proposed DSS uses the AR technology, through smart glasses, to facilitate and secure the preparation of these drugs. Controlling the preparation process is done with the help of the voice since hands are busy. SmartPrep was co-developed by the research laboratory CRISTAL, GRITA research group and the software publisher Computer Engineering.

Keywords: Chemotherapy Drugs Preparation, Decision Support System, Augmented Reality, Voice Control.

1 Introduction

Since 2004, cancer has been the main cause of premature mortality in the world, in front of cardiovascular diseases. According to the National Cancer Institute (NCaI), in France, the number of new cancer types was about 382 000 and the number of cancer deaths has reached 157 400 in 2018 [1]. The mortality rate has been decreasing steadily for the past 25 years. However, cancers with a poor prognosis (with a 5-year survival rate of less than 33%) represents 31% of cancers in males and 17% in females. Research in the field of oncology is extremely active. The objective is to accelerate the emergence of innovation for the benefit of patients [2] [3] [4].

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University Hospitals are facing an increase in the number of preparations of chemotherapy both in and out-of-clinical trial. Preparations are becoming more and more complex. The demand for chemotherapeutic drugs is daily. Each day, different preparations are requested depending on the treatments prescribed for the patients. What makes the task even more difficult is that each patient requires a specific treatment, depending on his or her weight, the protocol prescribed, the stage of treatment, etc. In addition, the drugs have to be prepared with great precision, and any mistake could present a great risk on the patient's life. So, pharmacists are confronted every day with dozens of (sometimes very complex) recipes that require great vigilance and double checks during their preparation. This implies the need for an effective additional support for preparation and control processes [5] [6] [7] [8]. Thus, in order to cope with this increase in activity, the chemotherapy preparation units are searching for an effective solution for the preparation and control process support [9] [10]. This solution should be able to make patient management as safe as possible, reduce the time of the whole preparation process of and meet the proponent requirements.

The main aim of this paper is to present the design, the development and evaluation of SmartPrep, our decision support system using AR, which is intended to improve safety in the preparation of chemotherapy drugs in health organizations and specifically in a hospital pharmacy. Our approach is based on the introduction of a free-hands appliance to assist the operators and record their acts. SmartPrep makes complex operations safe by ensuring their conformity to pre-established protocols and so reduce the incidence of errors. Our software solution is integrated into AR glasses: from a preparation/administration protocol, it is possible to give a step-by-step guidance to the operator carrying out the preparation/administration, to photo-record (triggered by the operator himself) the different steps, to obtain on-line control and to archive photos in the drug-batch file compiled for any possible posteriori control. SmartPrep gives also the operator the possibility to interact with the environment through a voice command. Our solution is studied, developed, implemented and tested in collaboration with the pharmacy of the Hospital University Center (HUC) of Lille and connected to the software CHIMIO®[1] of Computer Egineering company, containing all information about chemotherapy circuit including preparation protocols.

2 State of the art

Technology has always been a key factor in logistics. AR has taken off since the emergence of Smartphones. It has been appearing everywhere and in various fields. It is seen as a revolutionary alternative to solutions, which have many limitations, especially in terms of functionality and comfort. AR can be defined as an interface between virtual data and the real world [11]. It is a technique that overlays to reality its digital representation updated in real time. It thus offers the user real-time interaction possibilities [12]. This technology is actively growing in the healthcare field. For example, it is used to model patients' organs and blood vessels in 3D, thus facilitating the learning and work of surgeons, particularly to create precise 3D reconstructions of tumors [13].

[1] https://www.computer-engineering.fr/applications/chimio/

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The AccuVein® scanner is another example. It can illuminate the veins in a patient's skin, helping nurses and doctors locate them before inserting a needle [14].

For the traceability and control of operations, several solutions are available: a double control by a second operator, a gravimetric control during preparation with the help of scales integrated into the workstation [15], discharge control with identification and quantification of the drug in the finished preparation using a standard analytical method (CLHP-UV for example) or dedicated equipment (UV-Raman QCPrep+ spectrometry for example), video assistance and control by camera [16]. These currently available solutions have several limitations. For example, a double control by a second operator implies considerable time consumption in terms of human resources from day to day, problems of reliability and an absence of traceability of the controlled elements. Finally, assistance and video control imply a high cost and the need to install equipment in the production zone as well as the presence of operators during its setting-up. A comparison of these different methods based on a SWOT analysis is available in a recent article dealing with current controls in the pharmacy context [17].

The proposed solution in this paper is to use AR glasses which display and reel off in the user's visual field information useful for making preparations as well as identifying the actions accomplished and the products used by the operator with the aim of preventing errors in real time and establishing the traceability of the completed operations. The interfaces present in the glasses help guiding the operators in their preparation tasks and warning them if errors are detected while at the same time limiting the workload. Information must therefore be presented in the simplest way and the best adapted to each user. The proposed DSS allows for an extension of the existing adaptation systems for AR, as the existing solutions only deal with WIMP interfaces (i.e., Windows, Icons, Menus, Pointing). Moreover, interaction is bidirectionally effective: it is not simply a question of displaying information (interface output) adapted to the user and his context of use but also of enabling him to interact with the system (interface input) especially in the case of error. This is an original approach in as far as a search in the Medline database for articles linked to «drug related problem and AR» and « medication error and AR» comes across only two articles linked to using an application for mobile phone for the purpose of training prescribers.

3 Current practices at Lille University Hospital Center (UHC)

At the UHC of Lille, the clinical trial circuit is presented in Figure 1. This circuit is composed of three main inter-connected blocs: administration and prescription (steps 1 and 8), verification and allocation (step 2) and preparation (steps 3 to 7). The circuit begins with the prescription of chemotherapy by the doctor, which is carried out in 2 formats:

- A paper format consisting of a pre-filled prescription specific to each clinical trial.
- A digital format based on CHIMIO® software for products prepared by the Centralized Cytotoxic Preparation Unit (CCPU) of the pharmacy.

In the Clinical Trials sector, after verification of its conformity, the printed prescription allows the allocation and dispensing of the vials needed for the preparation. The vials are then transferred and received after microbiological decontamination in the CCPU

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production area. They are later stored and packaged by patient and by test until pharmaceutical validation of the preparation. At the pharmaceutical validation station, the pharmacist/pharmacy intern carries out the computer data entry in storage of the vials and the pharmaceutical validation. The pharmacy assistant prepares the basket following the instructions on the paper preparation sheet and initials the preparation sheet.

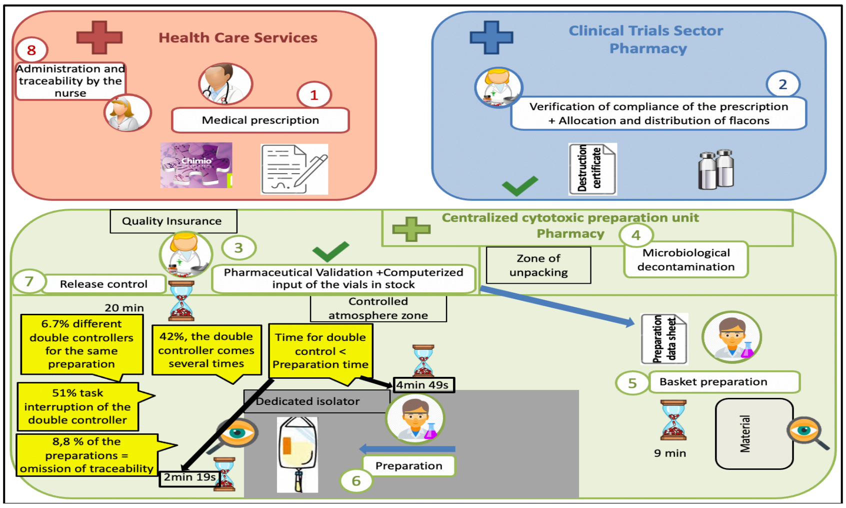

Figure 1: Circuit of injectable clinical trial preparations in cancerology before the implementation of SmartPrep

Each basket is double-checked by a third person, who initials the production sheet to ensure that all the necessary equipment and the appropriate vials are present. Sterilization is then performed to allow the basket to be transferred to the isolator dedicated to clinical trial preparations. After transfer into the isolator, the pharmacy assistant carries out the preparation following the instructions on the preparation sheet. The preparation steps are controlled by a second person with a traceability (initials) on the preparation sheet. The preparation is afterwards transferred to the Quality Insurance Room (QIR) with the associated preparation sheet and the vials used for control. After verification of the concordance between the preparation, the identity of the patient, the good conservation and the stability, the Registered Nurse administers the preparation. The evaluation of the ordinary chemotherapy drugs preparation circuit is presented in the following section.

4 Evaluation of the ordinary preparation process for injectable chemotherapy clinical trials at Lille HUC

4.1 Materials and methods

In order to evaluate the ordinary preparation and control circuit for injectable chemotherapy clinical trials (Figure 1), a data collection has been carried out with multiple

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objectives. The first purpose is to highlight any missing traceability of the preparation and control steps on the paper preparation sheets. A "traceability anomaly collection sheet" has been created to trace over a given period, all the traceability omissions detected on the preparation sheets at the time of pharmaceutical release. The second objective is to highlight the parameters that influence the preparation time and to achieve a time impact for the double visual inspection. For this data collection, clinical trials were selected to have a representative panel of preparations according to the presence or not of a reconstitution, the nature of the final packaging and thus the complexity of the operating procedure and the presence of the observer. The third objective is to highlight the interruptions of tasks in the preparation area related to the double visual control through the same data collection. In order to collect data on the functioning of the chemotherapy preparation unit, we rely on three sources of information:

- The "Sterilization Start Time Collection Sheet": This sheet is placed at the entrance to the isolators and as soon as a clinical trial chemotherapy preparation is introduced into the isolator for sterilization, the sheet is completed. Each line corresponds to a preparation with its order number, the time of the start of sterilization, the sterilization workstation used, and the number of diverse preparations placed in this workstation.
- The "Clinical Trial Preparations Observation Sheet": It tracks the progress of the chemotherapy preparation in the isolator. This form is completed on an observational basis by a person who acts as an external observer and is not involved in the preparation process or in the control of the preparation.
- The CHIMIO® software that provides information about:
  - the type of preparation: packaging, volume of active ingredient, whether or not a reconstitution step is necessary.
  - the time of the beginning and the time of the end of the preparation.
  - the number of preparations carried out during the day.

4.2 Results

In order to track and optimize the different phases of the preparation (basket preparation, preparation under isolator, double visual control and release control) five preparation times have been defined:

- Total processing time (TPT): the total time required to carry out the preparation from the reception of the vials to the validation of the release control.
- The basket preparation time (BPT): the time needed to prepare and double check the basket from the paper preparation sheet.
- The real preparation time (RPT): the time necessary for the operator to carry out the preparation in the isolator.
- The double-control time (DCT): the time during which a second person is called in to carry out the double visual control of the preparation. The second person can control several times the same preparation.

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- The release time (RT): the time required for the finished preparation to be checked, released and made available.

At the same time, a collection of all preparation anomalies or non-conformities are carried out. All this data is entered in a spreadsheet, whose schedule number serves as a link between the different sources of information. Analysis is handled by the PROSERPINE platform of the Faculty of Pharmacy of Lille University and are performed with SAS version 9.4 software (SAS Institute Inc., Cary, NC, USA). The data are presented as mean standard deviation or median [interquartile range] for continuous variables according to the asymmetry of their distribution, and as numbers (proportions) for categorical variables. The search for factors predictive of preparation and double control times was carried out with mixed linear regression models, with the variable ln-transformed (application of the Nerian logarithmic function) and including the manipulator and/or double controller as a random effects factor. The multivariate models are constructed in including all covariates, regardless of their degree of significance in univariate analyses. The selection of covariates is then done manually. The regression assumptions underlying the regression for the final multivariate model are verified graphically using residuals. For all analysis, p-value=0.05.

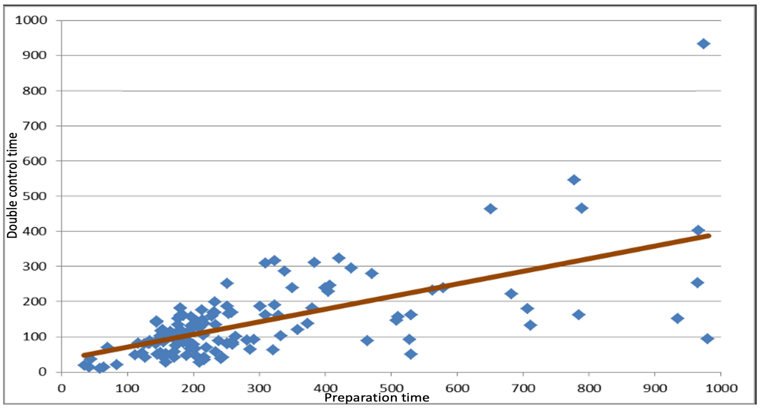

Figure 2: Double-control time (DCT) according to the real preparation time (RPT)

Figure 2 shows that the DCT is proportional to the RPT: the more the real preparation time increases, the more the double-checking time increases. We can easily explain that the lowest DCTs are associated with placebo preparations (average $\overline{X}$= 26s and standard deviation SD = 21s) and the longest with so-called "complex" preparations ($\overline{X}$= 421s and SD = 256s). We have also made a projection over one year of the time devoted to the double visual control of the preparations in clinical trials. For this purpose, we relied on the number of clinical trials carried out in 2018 (3673 preparations) and on the average time for double visual control (DCT). In total, it represents 145h/year equivalent to 8% of activity. This analysis shows the deficiencies of this preparation and control process. Therefore, in order to secure chemotherapy drugs preparation process and save time, further improvements are required.

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5 The new circuit of preparation of clinical trials in chemotherapy: AR technology Integration

5.1 Implementation of the new version of the software CHIMIO®

The aim here is to improve the safety of the entire preparation process, including chemotherapy clinical trials, and to prepare for the implementation of AR glasses as a tool to assist in preparation and control. It includes the implementation of a new version of CHIMIO® called "New Preparation", which targets to secure the preparation process by tracing each step and identifying each component of the preparation (vials, active ingredients, solvent, etc.), and to dematerialize the preparation spreadsheets.

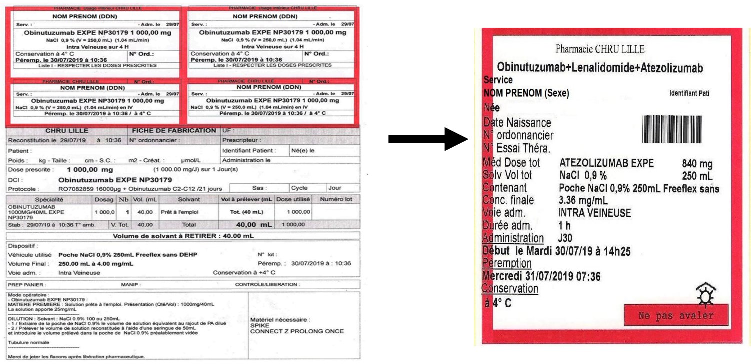

Figure 3: Evolution to the preparation label in the new chemotherapy drugs preparation circuit

Each preparation sheet is substituted by a digital form that is displayed on each workstation. The edition in paper format is reduced to the printing of the preparation label only (Figure 3) with a bar code corresponding to the order number. This latter allows to make an order between steps and to identify the content and the operating mode of the preparation.

5.2 Design of the new clinical trial preparation circuit

According to the usual preparation circuit of clinical trials in injectable chemotherapy presented in section 3 (figure 1: steps 3 to 7), we have made several modifications in order to be able to meet the requirements of AR integration (Figure 4). The improvements require the presence of data matrix (two dimentional square or rectangular pattern code) on the vials and on the solvent bags. As clinical trial vials do not have data matrix, a prior relabelling step is required. So, when the vials are entered into the computerized inventory by the pharmacist/pharmacy intern, a vial label edition is performed (Figure 5). The vial labels are then sent to the operator who re-labels the vials. Instead of the preparation sheets, preparation labels (Figure 3) are edited. As regards the preparation of the basket, it is based on a digital check list obtained from the bar code on

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the preparation label. This checklist corresponds to the vials and the material necessary to carry out the preparation in the isolator.

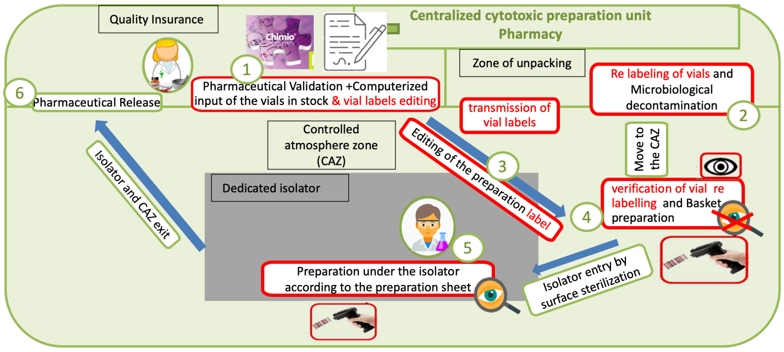

Figure 4: Improvements in the preparation circuit for chemotherapy clinical trials with the implementation of the "New Preparation Process".

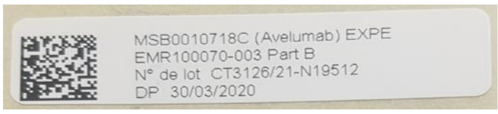

Figure 5: Example of label after re-labelling of the vials

In order to make the generation of the check list automatic for each preparation, a parameterization phase is necessary beforehand for each test. During preparation, the operator is identified by scanning a barcode on a badge, which ensures computerized traceability of the operator at each stage. Then, he scans the preparation label corresponding to the order number to access the computerized preparation sheet. During preparation, the control steps are modified: the pre-filled vials are checked by data matrix scanning. Only the control of volumes (reconstitution, purging and volume of active ingredient) remains carried out by a double visual control by a third person. In order to eliminate any omissions in traceability, the steps of the double visual control are traced at the IT level (identification of the double controller by name badge scanning). This step has been made obligatory for the validation of the end of the preparation. At the release control level, a control of the preparation is carried out via an access to the computerized preparation sheet. The steps of the double visual control appear on a release checklist. As regards the number of steps, those removed are the double visual control of the basket and at the preparation level the control of the vial(s) and the final packaging. As for the new steps added, they concern the relabelling of the pre-filled vials with the label edition.

5.3 Description of the process of a chemotherapy drug preparation with AR glasses

The preparation process is as follows: first of all, the operator wears glasses and is identified by scanning a personal data matrix. The glasses used are Optinvent ORA-2

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Smart Glasses (Figure 6) operating with Android 4.4. The proposed solution is transposable to any other Android AR technology.

Figure 6: The AR glasses used in SmartPrep

The identification of the preparation is done by scanning the specific barcode on the preparation label in the isolator. The operator can then see the protocol operating mode, step by step on the glasses in a comfortable way without obstructing his field of vision. The protocol is given by the CHIMIO® software.

Figure 7: Lille UHC Staff testing SmartPrep

To avoid the use of generic barcodes, the glasses are equipped with voice recognition (Section 7). At the end of the preparation, all the photos taken are saved as PDF files corresponding to the batch file of the preparation and archived at the level of the CHIMIO® software batch file. This file allows a posteriori control of the preparation thanks to the photos taken during the preparation. The different stages of the preparation and the photos taken can be configured before the preparation in the CHIMIO® software.This system allows a computerized identification of the operator, the realization of the preparation according to a step-by-step mode (which secures the preparation), a traceability of the stages of preparation and a suppression of the interruptions of tasks.

6 Image processing

Integrating image processing features enables an automated control of some preparation stages (e.g., control of the sample volume by analysing the photo of the syringe). Our objective is to integrate into operators ‘work environment information enabling them to reduce the risk of errors which may occur. According to the current preparation circuit analysis, the predominant factor was individual error (75.4%) followed by distraction or interruption (3.5%), insufficient training (2.9%), work overload (2.5%) and understaffing (2.3%). The access to this information is without disrupting completed tasks and without handling, mainly for reasons of hygiene and convenience. In order to automate the monitoring of the quality of each preparation phase, we have chosen to

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use the camera of the AR glasses to take pictures of each sample and to use a program to measure directly on the image the volume of the sample.

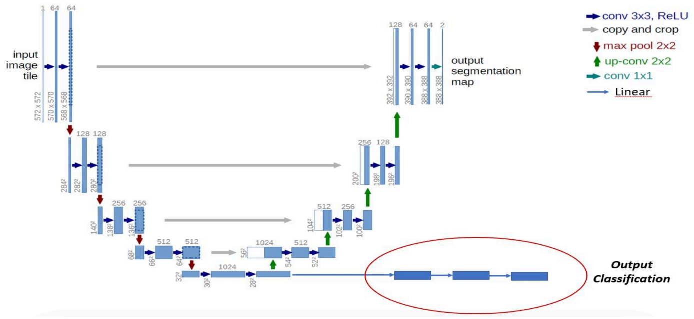

Figure 8: Contour recognition of syringes: Output classification

The validation is made afterwards with the double control. The algorithm used involves machine learning via the UNet model implemented with the Python Pytorch module. This program allows, in particular, to learn an artificial intelligence how to recognize particular outlines (Figure 8). In our situation, the program is trained to recognize the outlines of the syringes: the outline corresponding to the volume of the drug and the outline corresponding to the total volume of the syringe. Thus, the program recognizes the type of syringe used and the ratio between drug volume and total volume. From an image (input), it makes both a segmentation (output contour) and a classification (output type of syringe).

Figure 9: Photos of a syringe taken by the glasses

For the database, in order to have a reasonable amount of data (images of syringes with a certain amount of liquid), we took 2-minute videos at the pharmacy for each type of syringe. These videos were then sequenced and cut into images to be processed by the program. For each of these images, we traced the outlines corresponding to the volume of the drug and the total volume of the syringe (Figure 9).

The ratio is the one between the surface area corresponding to the drug and the surface area corresponding to the capacity of the syringe. To optimize the speed of learning, we used an online GPU which allows to save time; learning with this GPU took only a few hours. The results of the training on our database are represented by: XXXX_Y_Z where XXXX is the image number, Y is the recognized syringe type, Z is the ratio. Figure 10 shows that the result is relatively good: it is a syringe type 5; the ratio is between 0.83 and 0.73. The histogram of the figure 10 gives the distribution of the measurement values given by the program on a set of images from our database. Ideally, this histogram should be as close as possible to a Gaussian curve centred around the real value.

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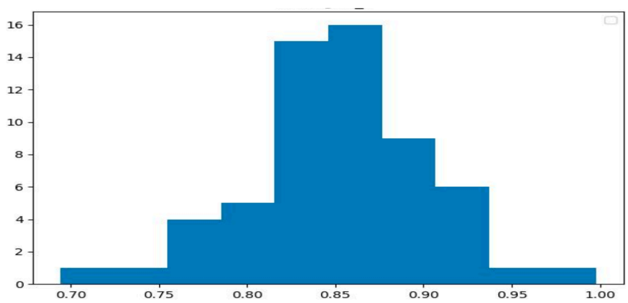

Figure 10: Distribution of the measured values given by the program on a set of images from our database

The closer the histogram is to a Gaussian curve with a small standard deviation, the better the program performs. To improve accuracy, the database must be provided with relevant images. The program containing the learning phase is coded in Python. It uses modules specific to this language and is consistent from a storage viewpoint. This is why the learning program is not directly implemented in the Android program; a connection is then established between the glasses and an external computer server. An Android program function sends the photos taken to the image processing program which, once the processing is done, returns the measured value that will be compared to the set value.

7 Preparation Voice Control

Recently, many companies like Google and Android have introduced voice control applications to facilitate the phone navigation to people with reduced mobility [18], [19], [20], or even to control applications using Siri, Google Assistant, or Cortana [21], [22]. Some researchers have studied real-time control of critical operations of mobile devices [23] and even of the entire Android operating system [24]. In the case of SmartPrep, we use the library Droid Speech which supports continuous voice recognition and can be also used offline if the speech package is installed in the device. We have implemented recognition of the following commands: (1) "next" – validates the current step and passes to the following one; (2) "previous" – goes back to the previous step; (3) "camera" – turns on the camera; (4) “pause” – interrupts the preparation in the case of preparation with a pause time after reconstitution; "photo" – takes a photo; (5) "back" – turns off the camera and goes back to the preparation steps.

7.1 Connection of the SmartPrep to CHIMIO® software

Developed by computer engineering, CHIMIO® software is a safe and easy tool for the implementation of healthcare protocols. Thanks to this tool, the pharmacy team has access to a dematerialization sheet which will allow to guide them in their activities. It is used everywhere in France and thus by the Pharmacy of Lille UHC as well. In summary, all information related to different parts of the chemotherapy circuit (patient,

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doctor, pharmacist, treatment...) is stored and managed by CHIMIO®. For the integration of the developed decision support system SmartPrep, we established a connector between CHIMIO® and the glasses, in order to retrieve automatically the processing steps. Since this information is stored on a web server, a web service is required to retrieve it (Figure 11).

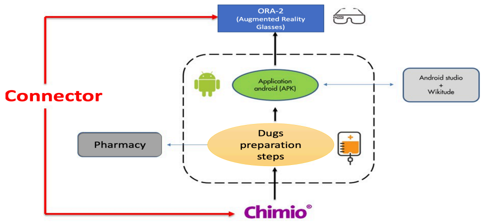

Figure 11: The connector functioning between CHIMIO® and SmartPrep

A web service is a technology that allows applications to dialogue remotely via Internet, and this independently of the platforms and languages on which they are based. This communication is based on the request and response concept, carried out notably with http, XML messages. According to Computer Engineering, a web service was implemented in 2017 to facilitate the "exchange of data between the CHIMIO® software and external preparation systems". Therefore, it is used to retrieve all information concerning the preparations (operating procedures). The chosen web service is "Geocode" developed by Google, allowing to have geolocation coordinates from a specific postal address. We chose this web service in particular because it is of the same architecture (REST) and returns the same type of file (JSON, XML) as the web service corresponding to the CHIMIO® software. Tests were performed on Android Studio and were successful. Then we get the response, and we swap it with the example operating mode to carry out the following treatments as the steps of separation and display.

8 Evaluation

The objective of the evaluation protocol is to qualify the whole SmartPrep system which is used in an environment with which it will interact, through an Interface, and from which a performance is expected. One of the requirements for the implementation of AR glasses is the wireless network and the implementation of the CHIMIO® New preparation version. SmartPrep has been implemented in the pharmacy of Lille UHC on July 22, 2019. As after each implementation, a learning phase is necessary. During this period, data collection cannot be carried out in order not to introduce a bias in our data which would make the results unusable. Nevertheless, initial tests have been carried out. AR glasses were used in the preparation area on fictive preparations (Figure 7). These tests helped us to validate the voice commands, the way to display of the protocol steps and the lecture of the protocol. After the tests, we could also be sure that the use of the AR glasses for the preparation under isolator (with the glass) is not problematic. The first tests carried out have proved the different concepts including the possibility of use in a complex environment (Wifi, Controlled Atmosphere Zone, through

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an isolator ...), the integration of information (preparation protocol to be followed step by step), the traceability of the key steps of the preparation with by taking photos and the connexion with the software CHIMIO®. AR glasses improve the security of clinical trials chemotherapy preparation. In fact, the preparation according to a step-by-step mode obliges the operator to respect a chronology. This is particularly interesting for clinical trials because for each study, preparations are not carried out on a daily basis. The traceability of the realization of the critical steps is also interesting by taking and storing photos. During tests, we observed that operators were becoming more and more at ease with the system. All the feedback we received from the operators has been very positive. They showed a real interest in the system. We distributed a satisfaction questionnaire after each test in order to evaluate the evolution of the preparers' satisfaction. The opinions and remarks are very positive and constructive.

9 Conclusion and perspectives

This work has enabled us to highlight the weaknesses of the current preparation circuit for injectable chemotherapy in clinical trials in the pharmacy of Lille HUC, particularly with regard to the double visual control itself and its impact on the preparation environment. AR glasses are an innovative solution to improve the preparation and control of chemotherapy preparations in clinical trials. This technology can be easily adapted to the preparation environment while securing preparations from the simplest to the most complex. SmartPrep can be used as a control solution for other types of preparations such as advanced therapy drugs or for clinical trial preparations beyond chemotherapy. It could also be used as a decision support system for any kind of drug preparation in health care services. Finally, in order to perfect the system and thus better satisfy user requirements, we are currently studying possible improvements to this decision-support system such as the appropriateness of adding more control steps and enhancing the learning system.

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